



# Louisiana Board of Pharmacy

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November 14, 2016

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

Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2016-2 – Pharmacists-in-Charge in Nonresident Pharmacies

Dear Senator Alario:

As we indicated in our first report to you on April 8, 2016, the Board is currently amending its rules to harmonize its eligibility requirements for pharmacists-in-charge in nonresident pharmacies to the same eligibility requirements for pharmacists-in-charge for in-state pharmacies. Those two eligibility criteria require the pharmacist-in-charge to have acquired at least two years of practice as a pharmacist in any jurisdiction within the United States, and further, requires the pharmacist-in-charge to be physically present in the pharmacy being supervised for at least twenty hours per week. Subsequent to our Notice of Intent published in the April 20, 2016 edition of the Louisiana Register, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on May 25, 2016.

We received no written comments or testimony prior to or during the public hearing or prior to the deadline for comments. However, we did receive one comment after the deadline. The Board considered those comments during their next meeting on August 10. Following that review, the Board determined that no revisions to the original proposed rule were necessary, 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 April 2016 Louisiana Register
- Summary of Comments from May 25, 2016 Public Hearing
- Commentator's Letter and Board Response
- 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 January 20, 2017 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

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

**NOTICE OF INTENT**

**Department of Health and Hospitals  
Board of Pharmacy**

**Pharmacist-in-Charge of Nonresident Pharmacy  
(LAC 46:LIII.2307)**

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 amend Chapter 23, Out-of-State Pharmacy, of its rules. In particular, the board proposes to amend §2307 relative to the requirements for the pharmacist-in-charge of a nonresident pharmacy. In addition, the board intends to make technical changes in the Chapter title and Section headings to change "out-of-state" to "nonresident."

**Title 46**

**PROFESSIONAL AND OCCUPATIONAL  
STANDARDS**

**Part LIII. Pharmacists**

**Chapter 23. Nonresident Pharmacy**

**§2307. Pharmacist-in-Charge**

A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.

1. The acquisition of the PIC privilege shall require:

a. possession of an active Louisiana pharmacist license;

b. possession of an active license in the state in which the pharmacy is located, and further, said license shall not have any restrictions which prohibit the position of pharmacist-in-charge;

c. active practice as a pharmacist for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and

d. the completion of the affidavit of responsibility and duties described in Subsection J of this Section.

2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week, the PIC shall be present and practicing at least 50 percent of the normal business hours.

B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.

C. - J. ...

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 18:1381 (December 1992), effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004, LR 33:1133 (June 2007), LR 42:

**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. The following statements are published in the *Louisiana Register* with the proposed agency Rule.

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 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. We anticipate no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

#### **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 exempt small businesses from compliance with any of the requirements.

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

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

4. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed Rule. The proposed Rule identifies the performance standards for the pharmacist-in-charge of a nonresident pharmacy, which is the same standard used for a pharmacy located within the state. The rules do not provide for alternative options for small businesses.

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 minimal costs to the provider to implement the requirements of the proposed Rule.

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.

#### **Public Hearing**

A public hearing on this proposed Rule is scheduled for Wednesday, May 25, 2016 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. The deadline for the receipt of all comments is 12 p.m. that same day.

Malcolm J. Broussard  
Executive Director

### **FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Pharmacist-in-Charge of Nonresident Pharmacy**

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

The proposed rule change will amend the existing requirements for the pharmacist-in-charge of a nonresident pharmacy. The proposed rule change will result in a cost of approximately \$2,000 for printing costs. This includes \$1,000 for the proposed rule change in FY 16 and \$1,000 for the final rule in FY 17.

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 change.

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

The persons directly affected by the proposed rule change are those pharmacists intending to serve as the pharmacist-in-charge (PIC) of a nonresident pharmacy. The change from the current rule will require the PIC to be physically present and practicing in the pharmacy for which he has accepted the PIC appointment. Another proposed change from the current rule identifies the minimum amount of time the PIC must be physically present in the pharmacy. These proposed standards already exist for pharmacies located within the state but do not currently exist in nonresident pharmacies. To the extent a current PIC of a nonresident pharmacy is not physically present for the minimum amount of time in the pharmacy, there may be additional personnel costs to the pharmacy.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will have no impact on competition or employment, unless a nonresident pharmacy has previously been relying on a 'phantom' PIC, i.e., a PIC not physically present in the pharmacy. In that case, there could be a positive effect on employment in that pharmacy.

Malcolm J. Broussard  
Executive Director  
1604#057

Evan Brasseaux  
Staff Director  
Legislative Fiscal Office



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Summary of Testimony & Public Comments  
re  
Regulatory Project 2016-2 ~ Pharmacist-in-Charge in Nonresident Pharmacies  
at  
May 25, 2016 Public Hearing

No comments were received prior to or during the public hearing or prior to the deadline.

We did receive a letter from John Rocchio on behalf of CVS Health after the deadline; it is included in the compilation for the Board's consideration.

On behalf of CVS Health, Dr. Rocchio objects to the proposed amendment requiring the pharmacist-in-charge to have acquired at least two years of licensed pharmacist practice, as well as to the proposed amendment requiring the pharmacist-in-charge to be physically present and practicing in the pharmacy for any period of time. In particular, the objection points to the potential for therapy interruption when the pharmacist-in-charge leaves that position and there is no qualified pharmacist-in-charge to replace the departing pharmacist.

May 25, 2016

Louisiana Board of Pharmacy  
Malcolm Broussard  
Executive Director  
3388 Brentwood Drive  
Baton Rouge, LA 70809

Dear Mr. Broussard,

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. CVS Health appreciates the opportunity to submit comments on the proposed amendments to LAC 46:LIII.2519, Medication Synchronization, and LAC 46:LIII.2307, Nonresident Pharmacist in Charge.

**Re: LAC 46:LIII.2519 Medication Synchronization**

CVS Health supports this amendment.

This amendment serves to assist pharmacists in aligning the often complex schedule of prescription medications to assist patients in adherence to treatment. CVS Health commends the Board on their efforts to enable pharmacists to adjust dispensed quantities to assist their patients, leading to fewer missed doses and better outcomes.

**Re: LAC 46:LIII.2307 Pharmacist in Charge**

CVS Health opposes these amendments.

CVS Health understands the Board has initiated the rulemaking process to amend LAC 46:LIII.2307 for the Pharmacist-in-Charge (PIC) of a nonresident pharmacy to require his or her physical presence in the pharmacy for a certain amount of hours per week and to have completed a minimum duration of licensure.

These amendments, specifically A(1)(c) and A(2), place requirements on a nonresident PIC that while on its face appear to be equivalent to the requirements for an in-state PIC, but in effect put a disproportionate burden on a nonresident pharmacy when compared to the effect of the proposed amendment to an in-state pharmacy.

A nonresident pharmacy, by the nature of being located outside of the state of Louisiana, would have a limited number of Louisiana licensed pharmacists as compared to pharmacies within Louisiana. Therefore, when a nonresident pharmacy experiences the turnover of the Louisiana nonresident PIC, the pharmacy may have to cease dispensing to the residents of the state of Louisiana until the Louisiana nonresident PIC is replaced. This existing hardship is compounded by the proposed amendments limiting the pool of viable nonresident PIC candidates to those that have practiced for 2 years and that meet the minimum hourly on site requirements. The ensuing



delay of identifying a successor could cause an immediate impact to patient safety with the potential resultant lapse in therapy.

Any disparate application of regulations, that burdens interstate commerce without the benefit of protecting the safety or health of the citizens of the state of Louisiana, is subject to scrutiny under the Commerce Clause of the United States Constitution. CVS Health strongly believes that the application of the in-state licensure duration requirement, as well as, the in-state physical presence in the pharmacy for a certain amount of time per week requirement would burden nonresident pharmacy practice disproportionately to in state pharmacy practice. We ask the Board to weigh the benefit of added requirements to nonresident PIC licensure compared to the potential negative effect on the residents of the state of Louisiana, and to provide clarity around the specific patient safety concerns which prompted the amendments.

CVS Health appreciates the opportunity to submit comments for the proposed amendments. It is our strong recommendation that the Board of Pharmacy carefully study the value of requiring a nonresident PIC to meet in state requirements compared to the potential safety and health issues that may occur when the inevitable lapse of therapy occurs. It is our belief that the proposed amendments to chapter 2307 place an additional, disproportionate burden on nonresident pharmacies compared to Louisiana pharmacies. CVS Health would welcome the opportunity to participate in a joint Board of Pharmacy and industry work group to review current nonresident permit requirements. If you have any questions or require additional information, please contact me directly at 617-599-9091.

Sincerely,

A handwritten signature in blue ink that reads "John N. Rocchio".

John N. Rocchio PharmD. RPh.  
Director, Pharmacy Regulatory Affairs

## Malcolm J. Broussard

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**From:** Malcolm J. Broussard  
**Sent:** Tuesday, May 31, 2016 10:46 AM  
**To:** 'Rocchio, John N.'  
**Subject:** RE: CVS Health Comments

Dr. Rocchio,

This will confirm receipt of your letter in our office on Thursday, May 26, 2016. I will relay your comments to the Board for their consideration; however, I am obliged to inform them your letter arrived after the deadline for receipt of such comments.

Thank you for your interest in our rulemaking process.

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy  
3388 Brentwood Drive  
Baton Rouge, LA 70809-1700  
United States of America  
Telephone +1.225.925.6481  
Telecopier +1.225.923.5669  
[mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov)

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**From:** Rocchio, John N. [<mailto:John.Rocchio@CVSHealth.com>]  
**Sent:** Thursday, May 26, 2016 7:12 AM  
**To:** Malcolm J. Broussard  
**Cc:** Rocchio, John N.  
**Subject:** CVS Health Comments

Malcolm,

I hope this message finds you well. I had hoped to provide the attached comments prior to the deadline yesterday but unfortunately matters did not work out as intended. That being said, I feel it is important to provide our thoughts on the amendments. Please let me know if you would like to discuss further or if you have any questions. Thank you and I hope to see you soon.

Sincerely,

John

John N. Rocchio PharmD. RPh.  
Director, Pharmacy Regulatory Affairs  
CVS Health  
Cell: 617-599-9091  
Fax: 401-733-0469



# Louisiana Board of Pharmacy

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November 13, 2016

John N. Rocchio, PharmD  
Director, Pharmacy Regulatory Affairs  
CVS Health  
One CVS Drive  
Woonsocket, RI 02895

Re: *Regulatory Project 2016-2 ~ Pharmacists-in-Charge in Nonresident Pharmacies*

Dear Dr. Rocchio:

The Board reviewed your May 25 letter during their August 10 meeting, taking note of your objections to the proposed revision of §2307 of the Board's rules. In particular, the proposed amendments would institute the same eligibility qualifications for the pharmacist-in-charge (PIC) position already required for pharmacies located within the state; i.e., (1) a minimum practice history of two years as a licensed pharmacist in any jurisdiction, and (2) a requirement for at least 20 hours per week physical presence in the pharmacy supervised by the PIC (or if the pharmacy is not open for 20 hours per week, then at least 50% of the total amount of time it is open for the week).

You indicated these requirements put a disproportionate burden on a nonresident pharmacy when compared to an in-state pharmacy due to the limited number of Louisiana licensed pharmacists. Further, you suggest the nonresident pharmacy may need to cease dispensing if there was a turnover in the PIC position, resulting in a potential lapse in therapy for patients. Finally, you indicated the proposed rules had no benefit in protecting the safety or health of the citizens of Louisiana.

The two eligibility criteria proposed in this rule were adopted for the pharmacies within the state in 2012. For several years prior to the promulgation of that rule, the Board encountered numerous pharmacists-in-charge in disciplinary proceedings who had less than two years of experience who simply had no concept of the responsibilities inherent in that management position. They were lured into those positions by financial incentives offered by the employer, but they simply did not have the practice experience necessary to competently manage the pharmacy. In other cases, the Board encountered pharmacists-in-charge attempting to manage a pharmacy *in absentia*, operating under a mistaken belief that document-based reviews were sufficient to properly manage a pharmacy operation. Contrary to your assertion, the Board is of the belief that a competent PIC is essential for the proper operation of a pharmacy in a manner that protects the public's health, safety and welfare.

Moreover, the Board's staff reports several pharmacies which experience turnover in their PIC position contact the Board office, which then works with the pharmacy; as long as the pharmacy shows forward progress in securing a replacement PIC, the staff does not require the pharmacy to cease dispensing activities in the interim.

The colleges and schools of pharmacy in the United States prepare pharmacists for entry-level practice. Competency for management requires additional experience, regardless of the state in which the pharmacy or pharmacist is located. The experience necessary to competently manage the pharmacy, as well as some minimal amount of time in the pharmacy to properly manage it, are both critical factors in the operation of the pharmacy in such a manner to protect the public's health and safety. Given the ability and history of the Board to work with pharmacies located in areas with difficult manpower supply issues, the Board is of the opinion the eligibility criteria for pharmacists-in-charge are reasonable and necessary for the protection of the public.

Thank you for your interest in the Board's rulemaking project. The Board has determined that no further amendments to the proposed rule are necessary, and further, has directed the continuation of the promulgation process. We will file our Second Report to the Joint Legislative Oversight Committee on Health and Welfare. We will transmit our usual Notice of Rulemaking Activity when that report is submitted.

For the Board:

A handwritten signature in cursive script that reads "Malcolm Broussard".

Malcolm J. Broussard  
Executive Director

**Louisiana Administrative Code**

**Title 46 – Professional and Occupational Standards**

**Part LIII: Pharmacists**

**Chapter 23. Nonresident Pharmacy**

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**§2303. Nonresident Pharmacy Requirements**

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**§2305. Nonresident Permit Requirements**

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**§2307. Pharmacist-in-Charge**

- A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege:
  - 1. The acquisition of the PIC privilege shall require:
    - a. Possession of an active Louisiana pharmacist license;
    - b. Possession of an active license in the state in which the pharmacy is located, and further, said license shall not have any restrictions which prohibit the position of pharmacist-in-charge;
    - c. Active practice as a pharmacist for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and
    - d. The completion of the *Affidavit of Responsibility and Duties* described below.
  - 2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week, the PIC shall be present and practicing at least 50 percent of the normal business hours.
- B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.
- C – J. ...

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 18:1381 (December 1992) effective January 1, 1993, amended LR 29:2100 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), amended LR

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**§2317. Nonresident Pharmacy Closure Procedures**

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