



Louisiana Board of Pharmacy

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September 8, 2015

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 2015-7 ~ Remote Processor Permit

Dear Senator Alario:

As we indicated in our first report to you on July 9, 2015, the Board is currently amending its rules to develop a new type of pharmacy permit that will allow the pharmacy to offer clinical services to the exclusion of dispensing prescription drugs. Subsequent to our Notice of Intent published in the July 20, 2015 edition of the *Louisiana Register*, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on August 26, 2015.

We received no written comments; however, we did receive one verbal comment during the hearing from a representative of the Louisiana Hospital Association. The LHA representative was supportive of the Board's proposed rule as published. 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 July 2015 *Louisiana Register*
- Summary of Comments from August 26, 2015 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 October 20, 2015 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

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 and Hospitals Board of Pharmacy

Remote Processor Permit (LAC 46:LIII.1143, 2431, 2433, 2435 and 2437)

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 Section 1143 and adopt Subchapter D—Remote Processor Pharmacy, of Chapter 24, that will enable the establishment of remote processor pharmacy sites within the state.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 11. Pharmacies

Subchapter D. Off-Site Services

§1143. Remote Processing of Medical Orders or Prescription Drug Orders

- A. - A.2.a. ...
- b. Repealed.

B. - C.2.c. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), amended LR 38:1240 (May 2012), LR 39:313 (February 2013), LR 41:

Chapter 24. Limited Service Providers

Subchapter D. Remote Processor Pharmacy

§2431. Purpose

A. The purpose of this Subchapter is to establish standards for the operation and regulation of remote processor pharmacies to be located within the state of Louisiana.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:

§2433. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section.

On-Site Pharmacy—a permitted pharmacy which utilizes remote processing services from a remote processor pharmacy.

Remote Processing Services—the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:

- a. receipt, interpretation, or clarification of an order;
- b. data entry and information transfer;
- c. interpretation of clinical data;
- d. performance of drug utilization review; and
- e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.

Remote Processor—a pharmacy holding a remote processor pharmacy permit and provides remote processing services for another permitted pharmacy,

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:

§2435. General Requirements

A. Authority and Limitations

1. A remote processor pharmacy permit shall authorize the permit holder to engage in remote processing services.

2. A remote processor pharmacy permit shall not authorize the procurement or possession of any prescription medications or any controlled substances.

3. The holder of a remote processor pharmacy permit shall not be eligible to acquire a Louisiana controlled dangerous substance license or a federal registration from the U.S. Drug Enforcement Administration.

B. Licensing Procedure

1. A person or other entity intending to operate a remote processor pharmacy shall complete the application form supplied by the board, and then submit it with any required attachments and the application fee to the board.

2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.

3. A person or other entity who submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2) and shall be subject to disciplinary action by the board.

4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.

5. Regardless of the date issued, the pharmacy permit shall expire on December 31 of every year. No person or other entity may operate a remote processor pharmacy with an expired permit; the continued operation of a remote processor pharmacy with an expired permit shall substantiate a violation of R.S. 37:1241(A)(12).

C. Maintenance of Permit

1. A remote processor pharmacy permit shall be valid only for the person or other entity to whom it is issued, and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the physical location for which it was issued.

2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such, and it shall not serve or be used as an additional or second permit.

D. Closure of Permit

1. When the owner of the permit intends to close the remote processor pharmacy permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with Section 1133 of the board's rules.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:

§2437. Standards of Practice

A. Environmental Standards

1. The remote processor pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.

2. The pharmacy shall be well-lighted, well ventilated and in compliance with the Louisiana *Sanitary Code*.

3. The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry by any unauthorized personnel.

4. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.

B. Staffing Requirements

1. The pharmacist-in-charge shall be a Louisiana-licensed pharmacist who is accountable to the board for compliance with the provisions of Section 1105 of the board's rules.

2. The pharmacist-in-charge shall assemble and manage a staff of appropriately-credentialed people as necessary to perform its work in a safe manner.

3. For those pharmacies using pharmacy interns, pharmacy technicians, and pharmacy technician candidates, the staffing ratios cited in the board's rules are applicable to those types of personnel.

C. Operations

1. The remote processor pharmacy shall comply with the provisions of Section 1143 of the board's rules.

2. The remote processor shall comply with the recordkeeping provisions of Section 1123 of the board's rules.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:

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 will be 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 positive 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 Statement

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 operational standards for the remote processor pharmacy site, but there is flexibility in how the small business achieves compliance with those standards.

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 Tuesday, August 26, 2015 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 noon that same day.

Malcolm J. Broussard
Executive Director

potential to facilitate competition with such sites located in other states as well as the potential for a positive effect on employment.

Malcolm J. Broussard
Executive Director
1507#067

Gregory V. Albrecht
Chief Economist
Legislative Fiscal Office

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Remote Processor Permit

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

The proposed rule will result in a cost of approximately \$2,000 for printing costs of the proposed and final rules in FY 16. The proposed rule will create a new classification of limited services pharmacy permit, for the purpose of enabling the establishment of remote processor pharmacy sites.

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

The proposed rule may result in an indeterminable increase in fees and self-generated revenues to the Board of Pharmacy. The cost of a new pharmacy permit is set at \$150 by statute while a renewal permit is set at \$125. The Board of Pharmacy does not anticipate issuing a large number of permits.

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

The proposed rule will create a new classification of pharmacy permit known as remote processor pharmacy sites. This type of pharmacy permit will not be authorized to procure or possess drugs for dispensing to patients, but they will be authorized to provide clinical services for other pharmacies, specifically the remote processing of medical orders or prescriptions for other pharmacies. The cost to establish and operate this type of pharmacy will be substantially less than the cost to operate a basic community pharmacy due to the absence of drug costs; however, there could be significant technology or communication costs.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will enable the establishment of remote processor pharmacy sites within the state which has the



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Summary of Testimony & Public Comments
re
Regulatory Project 2015-7 ~ Remote Processor Permit
at
August 26, 2015 Public Hearing

1. Rebecca D. Dowdy, MBA, Vice President, Louisiana Hospital Association.

Indicated verbal support for the proposed rule as published.

2. Richard Palombo, Senior Director of Pharmacy Regulatory Affairs, Express Scripts

Questioned whether the rule was intended for in-state pharmacies only, to which we replied and directed him to §2431 of the proposed rule, which indicates the proposed rule is intended for pharmacies located within the state of Louisiana.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter D. Off-Site Services

§1143. Remote Processing of Medical Orders or Prescription Drug Orders

A. – A.2.a. ...

- b. ~~In the event the pharmacy providing the remote processing services performs such services for a hospital pharmacy, the performance of all such services shall be limited to licensed pharmacists-[Repealed].~~

B. – C.2.c. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), amended LR 38:1240 (May 2012), amended LR 39:313 (February 2013), amended LR

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 - Performance of drug utilization review; and
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