



Louisiana Board of Pharmacy

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



March 19, 2012

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 2011-1 ~ Pharmacist-in-Charge (PIC) Requirements
Report No. 2 of 3 for Regulatory Project 2011-2 ~ Cognitive Services
Report No. 2 of 3 for Regulatory Project 2011-7 ~ Penal Pharmacy
Report No. 2 of 3 for Regulatory Project 2012-1 ~ E-Communications
Report No. 2 of 3 for Regulatory Project 2012-2 ~ Hospital Pharmacy
Report No. 2 of 3 for Regulatory Project 2012-3 ~ Remote Processing of Medical Orders

Dear Senator Alario:

As we indicated in our first report to you on January 10, 2012, the Board is currently promulgating amendments to six different sections of its rules as described above. Subsequent to our Notices of Intent published in the January 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 February 28, 2012.

The Board received one comment and suggestion relative to the Cognitive Services proposal from a representative for MEDCO Health Solutions, as well as a letter and verbal testimony relative to the Remote Processing of Medical Orders proposal from a representative for Rx Remote Solutions. Copies of the comments and the Board responses to each are enclosed within this report.

The Board has 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 a summary memo identifying the commentators, copies of those comments and the responses thereto, and then copies of the Notice of Intent and full text of the proposed rule for each of the six regulatory projects.

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 May 20, 2012 edition of the *Louisiana Register*. If you have any questions about the enclosed information or our procedures, please contact me directly at 225.925.6481 or mbroussard@pharmacy.la.gov.

For the Board:

Malcolm J. Broussard
Executive Director



Louisiana Board of Pharmacy

3388 Brentwood Drive
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MEMORANDUM

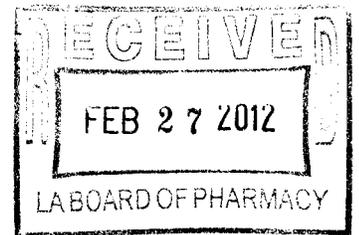
To: Joint Legislative Oversight Committee on Health & Welfare
From: Malcolm Broussard
Date: March 19, 2012
Re: Compilation of Comments from February 28, 2012 Public Hearing

With respect to the following regulatory projects, the Board received no comments or testimony:

- Regulatory Project 2011-1 ~ Pharmacist-in-Charge (PIC) Requirements
- Regulatory Project 2011-7 ~ Penal Pharmacy
- Regulatory Project 2012-1 ~ E-Communications
- Regulatory Project 2012-2 ~ Hospital Pharmacy

With respect to Regulatory Project 2011-2 ~ Cognitive Services, the Board received one written (e-mail) comment, from a representative of MEDCO Health Solutions. His comment and the Board's response is the first set of documents following this memorandum.

With respect to Regulatory Project 2012-3 ~ Remote Processing of Medical Orders, the Board received one written comment and verbal testimony in support of that written comment from an attorney representing Rx Remote Solutions, Inc. Their letter and the Board's response is the second set of documents following this memorandum.



To: Malcolm J. Broussard
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

PUBLIC COMMENTS ON NOTICE OF INTENT
REGULATORY PROPOSAL 2012 – 3
REMOTE ORDER PROCESSING

On behalf of Rx Remote Solutions, Inc. (“Rx Remote”), these written comments are submitted in response to the Louisiana Board of Pharmacy’s (the “Board”) January 20, 2012 Notice of Intent to amend LAC 46:LIII.1143 and 1525 related to Remote Order Processing. According to the Notice of Intent, the proposed amendments will permit hospital pharmacies to engage in remote processing of medical orders at any time of the day, instead of the current restriction to when one of the pharmacies is closed for the day. However, the proposed amendments do not address an inconsistency in the definitions of “Remote Dispensers” and “Remote Processors,” which should be reconciled by the Board through the rulemaking process. These comments address the need for this reconciliation.

Currently, the Board defines "Remote Dispenser" in LAC 46:LIII.1139 as, “a **Louisiana permitted pharmacy** which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.” Currently, the Board defines a “Remote Processor” as “a **permitted pharmacy in Louisiana** which provides remote processing services for another permitted pharmacy in Louisiana.” These definitions are worded differently and make it unclear as to whether the difference is immaterial. Since 2009, the Regulation Revision Committee has proposed to amend the definition of “Remote Processor” to make the definition more consistent with “Remote Dispenser.” Regulatory Proposal 2009-5 amended “Remote Processor” to be “a Louisiana permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana.” Regulatory Proposal 2011-6 defined “Remote Processor” as: “a pharmacy

permitted by the board which provides remote processing services for another permitted pharmacy in Louisiana.” However, the Board declined to approve both of these recommendations of the Regulation Revision Committee. *See* Minutes of 05-06-2009 and 11-16-2011 Board Meetings.

The definitions of “Remote Dispenser” and “Remote Processor” should be amended so that both use the phrase “Louisiana permitted pharmacy”, to provide for equal treatment and to prevent inconsistent interpretations. The definition of a “Remote Dispenser” clearly provides that the remote dispenser must have a Louisiana permit, because “Louisiana” appears before the word “permitted.” However, the definition of “Remote Processor,” as currently written, does not expressly require a Louisiana permit because “Louisiana” does not appear before “permitted pharmacy” in the definition. Instead, using the phrase “a permitted pharmacy in Louisiana,” could be interpreted to mean any pharmacy with a permit from any state as long as the pharmacy is located in Louisiana. As such, the current definition of “Remote Processor” is vague and may result in unintended consequences. Further, a rule can be deemed unconstitutionally vague if reasonable persons can differ as to its meaning and application.

To the extent that the current definitions could be interpreted to allow a remote dispenser to be physically located outside of Louisiana, while requiring a remote processor to be physically located inside of Louisiana, results in a negative impact to interstate commerce. If this Board denies a remote processor located out-of-state the ability to provide remote processing services to pharmacies located within Louisiana, the Board may be engaging in economic protectionism and discrimination in direct violation of the dormant Commerce Clause. *See* U.S. Const. Art. I §8, cl. 3; *Wyoming v. Oklahoma*. 502 U.S. 437, 454, 112 S.Ct. 789, 800 (1992). The current discrepancy between the definition of “Remote Dispenser” and “Remote Processor” should be amended to remove the possibility of discrimination against out-of-state remote processors.

The Board may want to look to the National Association of Boards of Pharmacy's Model Rules ("Model Rules"), which provide for Remote Pharmacy Services. *See* Model Rules for the Practice of Pharmacy, Section 3, Pharmacy Practice (o). The Model Rules do not require a remote processor to be physically located in the state in which it is providing remote processing services, but instead provide that the remote processor "shall apply to the Board for a permit." *Id.* Rx Remote has no objection to the Board imposing a requirement that any remote processor must obtain a Louisiana permit. Rx Remote is prepared to meet all of the requirements to become a Louisiana-permitted pharmacy.

Further, if the current definitions allow a remote dispenser to be physically located outside of Louisiana, but require a remote processor to be located inside of Louisiana, such application is contrary to general principles of public safety. An out-of-state dispenser presents a greater threat to patient safety than that of a remote processor because a remote processor, unlike a remote dispenser, does not physically fill the prescriptions. Remote order processing helps hospitals and other healthcare facilities achieve twenty-four hour, seven-day-a-week pharmacist coverage to review medication orders thereby improving patient care, avoiding medication errors, and decreasing the need for nursing over-rides that result from the use of automated dispensing machines, when pharmacies, such as hospital pharmacies, are physically closed.

Rx Remote respectfully requests that the Board reconsider Regulatory Proposal 2012 – 3 and re-issue its Notice of Intent, stating an intention to adopt an amendment to the definition of "Remote Processor" in LAC 46:LIII.1139 as previously proposed by Regulations Committee: "a Louisiana permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana." The suggested amendment to the definition of "Remote Processor" will resolve the current inconsistency with the definition of "Remote Dispenser," prevent any dispute as to whether a Louisiana permit is required, and resolve any potential Constitutional issues.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Linda G. Rodrigue", written over a horizontal line.

Linda G. Rodrigue

Jennifer Jones Thomas

Kean Miller, LLP

400 Convention Street, Suite 700

Baton Rouge, LA 70801

(225) 387-0999

Attorneys for Rx Remote Solutions, Inc.



Louisiana Board of Pharmacy

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March 19, 2012

Jennifer J Thomas
Kean Miller LLP
400 Convention St Ste 700
Baton Rouge LA 70801

Re: Comments & Testimony re Regulatory Project 2012-3 ~ Remote Processing of Medical Orders

Dear Ms. Thomas:

This will confirm the receipt of your written comments in our office on February 27, as well as your verbal testimony during our public hearing on February 28, wherein you offered comments in response to the Board's published Notice of Intent relative to the referenced regulatory project.

As indicated in the Notice of Intent, the proposed amendments will permit hospital pharmacies to engage in remote processing of medical orders at any time of the day, instead of the current restriction to when one of the pharmacies is closed for the day. The current rules contain a provision for remote processing at §1143. There is a separate provision for remote processing in hospital pharmacies at §1525, and it contains a limitation that requires one of the pharmacies to be closed at the time remote processing occurs. The Board proposes to repeal §1525 and maintain §1143 which allows all pharmacies engaged in remote processing to perform those services at any time of the day, whether or not one of the pharmacies is closed. This proposal will primarily benefit small rural hospitals that do not have 24-hour pharmacy services.

At the outset of your letter, you indicated your comments were intended to focus on what you perceived to be an inconsistency in the definition of two terms used in those rules: *Remote Dispenser* and *Remote Processor*, and indeed, there were no comments on the actual topic of the notice. You closed your letter with a request for the Board to interrupt the current project and re-issue another Notice of Intent that would address your perceived inconsistencies.

With respect to the different terms and their definitions, a *Remote Dispenser* is defined as a Louisiana permitted pharmacy, and a *Remote Processor* is defined as a permitted pharmacy in Louisiana. You took note of prior attempts to change the definition of Remote Processor to be the same as that of Remote Dispenser and the failure of those attempts.

From the second page of your letter:

The definition of a "Remote Dispenser" clearly provides that the remote dispenser must have a Louisiana permit, because "Louisiana" appears before the word "permitted." However, the definition of "Remote Processor," as currently written, does not expressly require a Louisiana permit because "Louisiana" does not appear before "permitted pharmacy" in the definition. Instead, using the phrase "a permitted pharmacy in Louisiana," could be interpreted to mean any pharmacy with a permit from any state as long as the pharmacy is located in Louisiana. As such, the current definition of "Remote Processor" is vague and may result in unintended consequences. Further, a rule can be deemed unconstitutionally vague if reasonable persons can differ as to its meaning and application.

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PMP Office
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Executive Office
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Your suggestion that one interpretation of the term "Remote Processor" could mean any pharmacy with a permit from any state as long as the pharmacy is located in Louisiana is contrary to current pharmacy law and rule. In particular, we draw your attention to the very same chapter of rules (Chapter 11), specifically at §1101.A:

§1101. Pharmacy

- A. *Qualification. Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescription drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.*

Further, we remind you that no pharmacy may operate within Louisiana until it is licensed by the Louisiana Board of Pharmacy, as specified by La. R.S. 37:1221:

§1221. Unlawful operation

- A. *No person shall open, establish, operate, or maintain a pharmacy, located within this state, unless the pharmacy is issued a permit by the board.*

Finally, we draw your attention to the definitions in the beginning of the Pharmacy Practice Act, specifically at La. R.S. 37:1164:

- (4) *"Board" means the Louisiana Board of Pharmacy.*

With the knowledge of how all the words are defined, it is clear that a Remote Dispenser – defined as a Louisiana permitted pharmacy – is a pharmacy that is licensed by the Louisiana Board of Pharmacy and is located either within the state or in another state. Similarly, a Remote Processor – defined as a permitted pharmacy in Louisiana – is a pharmacy that is licensed by the Louisiana Board of Pharmacy and is located within the state of Louisiana. We respectfully suggest there is nothing vague about those terms, nor is there any inconsistency. We acknowledge you may disagree with the rule as to its effect, but there is no inconsistency. The terms are clearly defined.

With that explanation, the Board has taken notice of your desire to change the definition of Remote Processor. Specifically, we noted your attendance at the March 14 meeting of the Board's Regulation Revision Committee where you submitted a proposal to change the definition of that term to mirror that of Remote Dispenser. As you recall, the committee chair scheduled consideration of your request at the next committee meeting, scheduled for April 10-11.

At that March 14 meeting, you offered that while your client desires an expeditious resolution of his concern, he has no desire to delay the benefit that the small rural hospitals will derive from this regulatory proposal.

Given the absence of any comments on the actual topic of the notice of intent, as well as the initiation of parallel activities to address your client's concern, the Board has declined to interrupt the current regulatory project for the purpose of re-issuing another notice of intent to address your client's concern.

We appreciate the time and effort you have taken to review and comment on the Board's regulatory proposal, and we look forward to your continued participation in the development of a new regulatory proposal to address your client's concerns.

For the Board:



Malcolm J Broussard
Executive Director

Notice of Intent

Department of Health and Hospitals Board of Pharmacy

Remote Processing of Medical Orders

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 its rules relative to the remote processing of medical orders. In particular, the proposed amendments will permit hospital pharmacies to engage in the remote processing of medical orders at any time during the day.

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 Tuesday, February 28, 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

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

* * *

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

A. General Requirements

* * *

- 2. ~~With respect to hospital pharmacies and institutional pharmacies,~~ A contract or agreement for remote processing services shall not relieve the on-site pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services ~~within the hospital or institutional facility.~~ The activities authorized by this Section are intended to supplement ~~hospital and institutional~~ pharmacy services ~~when the pharmacy is not operating~~ and are not intended to eliminate the need for an on-site pharmacy or pharmacist.

* * *

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

* * *

Chapter 15. Hospital Pharmacy

* * *

§1525. Remote Processing of Medical Orders (repealed)

~~A. General Requirements~~

- ~~1. A hospital pharmacy may obtain remote processing services from a remote processor provided the pharmacies:~~

~~a.—Have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and~~

~~b.—Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.~~

~~2.—A contract or agreement for remote processing services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this Section are intended to supplement hospital pharmacy services when the pharmacy is not operating and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.~~

~~B.—Access to Patient Information~~

~~1.—The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the hospital pharmacist has access to when the pharmacy is operating. The remote pharmacist shall receive training in the use of the hospital's electronic systems.~~

~~2.—If a hospital pharmacy is not able to provide remote electronic access to the patient information system, both pharmacies shall have appropriate technology to allow access to the required patient information.~~

~~C.—Policies and Procedures~~

~~1.—Hospital pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall also be available for inspection and copying by the board.~~

~~2.—At a minimum, the manual shall include policies and procedures for:~~

~~a.—Identification of the responsibilities of each of the pharmacies;~~

~~b.—Protection of the integrity and confidentiality of patient information; and~~

~~c.—Maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such services.~~

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

CODING: Words in ~~struck through~~ type are deletions from existing rule; words underscored are additions.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), repealed LR