



Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov



July 9, 2015

Senator John A Alario, Jr, President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804-9183

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2015-8 ~ Remote Access to Medical Orders

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the Board's rules to allow hospital pharmacies to enable their staff pharmacists to remotely access the pharmacy's information system from home or any other location in order to review medical orders prior to the administration of the drug to the patient. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent
- Proposed Rule
- Family Impact Statement
- Poverty Impact Statement
- Provider Impact Statement
- Regulatory Flexibility Analysis
- Solicitation of Comments
- Fiscal & Economic Impact Statement

As indicated in the solicitation, we will convene a public hearing on August 26, 2015 to receive public comments and testimony on this proposal. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
Director, Community Outreach Services, La. Economic Development
Via Email: Pat.Witty@la.gov
Editor, Louisiana Register
Via Email: Reg.Submission@la.gov
Reference File

Notice of Intent

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

Remote Access to Medical Orders (LAC 46:LIII.1527)

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 *Chapter 15 – Hospital Pharmacy* of its rules by drafting a new §1527 – *Remote Access to Medical Orders*, to allow hospital pharmacies to enable their own pharmacists to remotely access the hospital's dispensing information system from any location for the purpose of processing medical orders.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 15. Hospital Pharmacy

...

§1503. Definitions

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

...

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

- ~~a. Receiving, interpreting, or clarifying a medical order;~~
- ~~b. Entering data and transferring medical order information;~~
- ~~c. Interpreting clinical data;~~
- ~~d. Performing therapeutic intervention relative to medication therapy; and~~
- ~~e. Providing drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs [Repealed].~~

~~*Remote Processor* – a permitted hospital pharmacy in Louisiana which provides remote processing services for another permitted hospital pharmacy in Louisiana [Repealed].~~

...

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 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007), amended LR 39:1282 (May 2013), amended LR 40:2256 (November 2014), effective January 1, 2015, amended LR

...

§1527. Remote Access to Medical Orders

- A. Notwithstanding any provision of rules to the contrary, nothing shall prohibit a Louisiana-licensed pharmacist who is an employee of or under contract with a hospital pharmacy in Louisiana from accessing that pharmacy's dispensing information system from a location other than the pharmacy in order to process prescription drug orders or medical orders, but only when all of the following conditions are satisfied:
1. The pharmacy establishes controls to protect the privacy and security of confidential records;
 2. The pharmacist does not engage in the receiving of written prescription drug orders or medical orders or the maintenance of prescription drug orders or medical orders; and
 3. No part of the pharmacy's dispensing information system is duplicated, downloaded, or removed from the pharmacy's dispensing information system.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, 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. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

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

IV. The effect on family earnings and family budget.

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

V. The effect on the behavior and personal responsibility of children.

We anticipate 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 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
FOR ADMINISTRATIVE RULES

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.

I. The effect on household income, assets, and financial security.

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

II. 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.

III. The effect on employment and workforce development.

We anticipate no positive impact on employment and workforce development.

IV. The effect on taxes and tax credits.

We anticipate no impact on taxes or tax credits.

V. 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.

PROVIDER IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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:

I. 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.

II. 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.

III. 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.

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 proposed rule does not exempt small businesses from compliance with any of the requirements.

II. 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.

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

There are no reporting requirements in the proposed rule.

IV. 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 hospital pharmacy to establish remote access for its pharmacists, but there is flexibility in how the small business achieves compliance with those standards.

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.

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 this proposed rule. A public hearing on this proposed rule is scheduled for Tuesday, August 26, 2015 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
(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 authorize pharmacist practicing at hospital pharmacies to access their pharmacy's dispensing information system from any location outside the pharmacy for the purpose of processing medical orders.

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 NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule will allow hospital pharmacies to enable their pharmacists to access the pharmacy's dispensing information system from any location outside the pharmacy for the purpose of processing medical orders. The proposed rule requires the establishment of policies and procedures to protect the privacy and security of confidential records. There may or may not be additional costs for the creation or maintenance of systems or procedures to facilitate the remote access to pharmacists. To the extent such pharmacies may currently be contracting with outside firms for the remote processing of their medical orders, this proposed rule may provide a more economical option by allowing either existing staff or new staff to remotely process those orders from their homes or other locations.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will authorize hospital pharmacies to allow their staff pharmacists to remotely access the pharmacy's dispensing information system from any location outside the pharmacy. This capability has the potential of replacing current contracts with other pharmacies for the purpose of remotely processing medical orders, which could have a positive effect on competition and employment.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement: **Malcolm J. Broussard** Dept.: **Health and Hospitals**
Executive Director
Office: **Board of Pharmacy**
Phone: **(225) 925-6481** Title: **Remote Access to Medical Orders**
Return Address: **3388 Brentwood Drive** Effective Date of Rule: **October 20, 2015 (est.)**
Baton Rouge, LA 70809

SUMMARY
(Use complete sentences)

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. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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 authorize pharmacists practicing at hospital pharmacies to access their pharmacy's dispensing information system from any location outside the pharmacy for the purpose of processing medical orders.

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

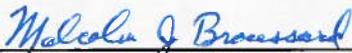
There will be no impact on revenue collections of state or local governmental units from the proposed rule.

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

The proposed rule will allow hospital pharmacies to enable their pharmacists to access the pharmacy's dispensing information system from any location outside the pharmacy for the purpose of processing medical orders. The proposed rule requires the establishment of policies and procedures to protect the privacy and security of confidential records. There may or may not be additional costs for the creation or maintenance of systems or procedures to facilitate the remote access to pharmacists. To the extent such pharmacies may currently be contracting with outside firms for the remote processing of their medical orders, this proposed rule may provide a more economical option by allowing either existing staff or new staff to remotely process those orders from their homes or other locations.

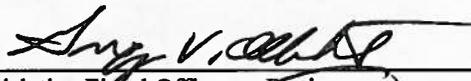
IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will authorize hospital pharmacies to allow their staff pharmacists to remotely access the pharmacy's dispensing information system from any location outside the pharmacy. This capability has the potential of replacing current contracts with other pharmacies for the purpose of remotely processing medical orders, which could have a positive effect on competition and employment.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee



Legislative Fiscal Officer or Designee

7/9/2015

Date of Signature

June 19, 2015

Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board proposes to amend *Chapter 15 – Hospital Pharmacy* of its rules to authorize hospital pharmacies to enable their pharmacists to remotely access the pharmacy's dispensing information system from any location outside the pharmacy for the purpose of remotely processing medical orders. A copy of the Notice of Intent is appended.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

As hospital pharmacies seek remote processing pharmacy providers, all of those providers are currently located in other states. The proposed rule seeks to provide an alternative option by authorizing the hospital pharmacies to allow their pharmacists to remotely access the pharmacy's dispensing information system from any location outside the pharmacy for the purpose of remotely processing the hospital's medical orders. The proposed rule identifies the requirements for this alternative option.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:

- (1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The Board anticipates an expenditure of approximately \$2,000 for the printing of the proposed and final rules. Those funds are budgeted and available from self-generated agency funds.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) ____ Yes. If yes, attach documentation.

(b) ____ No. If no, provide justification as to why this rule change should be published at this time.

The Board operates totally on self-generated funds.

- D. Compliance with Act 820 of the 2008 Regular Session

- (1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. To the extent that all of the pharmacies licensed by the Board may meet the statutory definition of a small business, there are 1,951 pharmacies currently licensed by the Board.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The proposed rule contains no requirements for reporting or record keeping.

- (3) A statement of the probable effect on impacted small businesses.

The proposed rule will enable small businesses to implement a less costly alternative to any contract for remote processing of medical orders.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 2,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
TOTAL	\$ 2,000	\$ 0	\$ 0
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The Board has allocated \$2,000 for the printing of the Notice of Intent and the Final Rule in FY 16.

3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 2,000	\$ 0	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
TOTAL	\$ 2,000	\$ 0	\$ 0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board has sufficient funds budgeted and available to complete the rulemaking project.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

To the extent a local governmental unit currently operates a pharmacy and also contracts with a non-resident pharmacy for remote processing services, it is possible the proposed rule may enable the pharmacy to allow its pharmacists to perform those same services from home or any other location, at a cost likely to be less than the cost for contracting those services to another pharmacy.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 15-16</u>	<u>FY 16-17</u>	<u>FY 17-18</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
TOTAL	\$ 0	\$ 0	\$ 0

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

Since the proposed rule does not impact fees, the Board discerns no impact on the revenue collections of state and local governmental units from the proposed rule.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule will allow hospital pharmacies to enable their pharmacists to remotely access the pharmacy's dispensing information system from any location outside the pharmacy for the purpose of processing medical orders. The proposed rule requires the establishment of policies and procedures to protect the privacy and security of confidential records. There may or may not be additional costs for the creation or maintenance of systems or procedures to facilitate the remote access to pharmacists.

To the extent such pharmacies may currently be contracting with outside firms for the remote processing of their medical orders, this proposed rule may provide a more economical option by allowing either existing staff or new staff to remotely process those orders from their homes or other locations.

Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

The proposed rule will have no impact on the revenue of a remote processor pharmacy since there are no fees identified within the proposed rule.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule will authorize hospital pharmacies to allow their staff pharmacists to remotely access the pharmacy's dispensing information system from any location outside the pharmacy. This capability has the potential of replacing current contracts with other pharmacies for the purpose of remotely processing medical orders, which could have a positive effect on competition and employment.



Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

June 19, 2015
Date of Signature