



Louisiana Board of Pharmacy

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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 2015-5 ~ Electronic Signature on Facsimile Prescription

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the Board's rules to delay the implementation of a rule adopted earlier this year relative to the use of electronic signatures by prescribers on prescriptions delivered by facsimile to pharmacies. This delay will provide additional time for the stakeholders to upgrade their technology and information systems to comply with the rules. You may recall we issued an Emergency Rule on this topic effective June 1. 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: Req.Submission@la.gov
Reference File

Notice of Intent

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

Electronic Signature on Facsimile Prescription (LAC 46:LIII.2511)

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 §2511 of *Chapter 25 - Prescriptions, Drugs, and Devices* of its rules, to allow pharmacies to accept – for a limited period of time – a facsimile prescription bearing an electronic signature of the prescriber.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 25. Prescriptions, Drugs, and Devices

...

Subchapter B. Prescriptions

§2511. Prescriptions

A – C.5.c ...

- d. The provisions of this Section notwithstanding, a prescription for a medication not listed as a controlled substance which is received in a pharmacy by facsimile and which bears an electronic signature of the prescriber shall be construed as a validly-formatted prescription; however, this temporary allowance shall expire at midnight on December 31, 2016.

C.6 – F. ...

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), amended LR 29:2102 (October 2003), effective January 1, 2004, amended LR 41:98 (January 2015), amended 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, and 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.

There are no reporting requirements in the proposed rule. Pharmacies are not required at this time to accept electronic prescriptions; however, the market is continuing to evolve in that direction.

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 allows, but does not require, pharmacies to accept electronic prescriptions.

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 allow pharmacies to continue to accept facsimile prescriptions bearing electronic signatures of the prescriber, but only for a limited period of time ending December 31, 2016.

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 directly affects those pharmacies which do not yet accept electronic prescriptions. The proposed rule also affects prescribers using prescription generating software systems that do not alert the prescriber when the electronic prescription generated and signed by the prescriber cannot be delivered to the intended pharmacy because it is unable to accept electronic prescriptions, and then further, converts the prescription to a facsimile format for delivery without alerting the prescriber. The time delay in the proposed rule is intended to give pharmacies additional time to upgrade their systems to accept electronic prescriptions, and further, to give vendors (and clients of those vendors) of prescription generating software additional time to upgrade their systems to notify the prescriber when their electronic prescriptions cannot be delivered electronically and to prohibit the subsequent conversion of that prescription for delivery to the pharmacy by facsimile.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There will be no impact on competition or employment from the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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

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 allow pharmacies to continue to accept facsimile prescriptions bearing electronic signatures of the prescriber, but only for a limited period of time ending December 31, 2016.

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IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There will be no effect on competition or employment from the proposed rule.

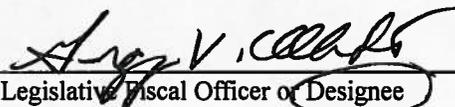


Signature of Agency Head or Designee

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

July 9, 2015

Date of Signature



Legislative Fiscal Officer or Designee

7/9/2015

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 §2511 of its rules to authorize pharmacies to continue to accept facsimile prescriptions bearing electronic prescriber signatures for a limited period of time. 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.

The Board revised its prescription rules in January 2015. These revisions established a minimum data set for prescriptions, codified contemporary standards, and harmonized federal and state requirements for prescriptions. Subsequent to the promulgation of the rule, the Board received feedback from multiple stakeholder communities about one particular aspect – prescriptions received by facsimile bearing electronic signatures in lieu of the required manual signature. It appears some prescribers are using software (or older versions thereof) that do not alert the prescriber when their electronically generated and signed prescription cannot be delivered electronically to the pharmacy and then converts the prescription to facsimile for delivery to the pharmacy. Federal standards require that failure alert for prescriptions for controlled substances and prohibit the conversion to facsimile for delivery. The Board's rule does not require the failure alert for prescriptions for non-controlled substances; however, electronic signatures are only valid for electronic prescriptions. The Board proposes to give the stakeholder communities additional time to achieve compliance through the temporary allowance provided in the proposed rule.

- 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.

For those pharmacies not yet able to accept electronic prescriptions, or for those prescribers using prescription generating software, there may – or may not – be a cost to upgrade their information systems to achieve compliance with the rule. It may simply be a matter of learning to use existing features in their systems.

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

The Board anticipates a minimal, if any, impact on small businesses.

- (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.

The proposed rule will not result in any cost savings to local governmental units.

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 directly affect any pharmacy which does not yet accept electronic prescriptions. The proposed rule will indirectly affect any prescriber using electronic prescription generating software that does not alert the prescriber when his system is unable to deliver that prescription electronically and then subsequently converts that prescription to facsimile format for delivery to the pharmacy by facsimile. Federal standards require the prescriber's software to alert the prescriber when the electronic prescription for a controlled substance cannot be delivered electronically to the pharmacy, and further, prohibits the conversion of that prescription to facsimile for delivery to the pharmacy. Federal standards permit electronic signatures for electronic prescriptions for controlled substances but require manual signatures for facsimile prescriptions. The Board's rules limit the use of electronic signatures to electronic prescriptions for all prescriptions.

The pharmacy that does not yet accept electronic prescriptions may choose to make a business decision not to do so. The ability to accept electronic prescriptions may require the acquisition of a new dispensing information system, which could bear a substantial cost, or it could require simply an upgrade to the current version of the system, which may or may not bear a cost, depending on the terms of the maintenance agreement with the vendor of the system.

Similarly, the prescriber using prescription generating software might need to change to a system that complies with the federal standard for prescribing controlled substances, or it may be simply an upgrade to the current version of the system that is in compliance with the federal standard for prescribing controlled substances. Further, the upgrades may or may not bear a cost depending on the terms of the maintenance agreement with the vendor of the system.

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.

There will be no impact on receipts and/or revenue from 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.

There will be no effect on competition or employment from the proposed rule.



Signature of Agency Head or Designee

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

July 9, 2015

Date of Signature