



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ Facsimile 225.925.6499  
[www.pharmacy.la.gov](http://www.pharmacy.la.gov) ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



May 7, 2015

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

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

## Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2015-3 ~ Electronic Product Verification

Dear Senator Alario:

The Board has initiated the rulemaking process to amend the Board's rules to allow pharmacies to use bar codes or other electronic product verification processes in lieu of the currently required manual product checking by pharmacists. 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 June 25, 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](mailto: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](mailto:APA.S-H&W@legis.la.gov)  
Speaker, House of Representatives  
Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)  
Chair, House Health & Welfare Committee  
Via Email: [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)  
Director, Community Outreach Services, La. Economic Development  
Via Email: [Pat.Witty@la.gov](mailto:Pat.Witty@la.gov)  
Editor, *Louisiana Register*  
Via Email: [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)  
Reference File

**Notice of Intent**

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

Electronic Product Verification (LAC 46:LIII.1217 and 1509)

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 §1217 of *Chapter 12 - Automated Medication Systems* and §1509 of *Chapter 15 - Hospital Pharmacy* of its rules, to allow pharmacies to use bar codes or other electronic product verification processes in lieu of the currently required manual product checking by pharmacists.

# Louisiana Administrative Code

## Title 46 – Professional and Occupational Standards

### Part LIII: Pharmacists

#### Chapter 12. Automated Medication Systems

...

#### **§1217. Stocking and Restocking; Electronic Product Verification**

- A. ...
- B. ...
- C. Electronic Product Verification.
  - 1. A bar code verification, electronic verification, or similar verification process may be utilized to assure the correct selection of drugs to be placed into an automated medication system.
  - 2. The use of a bar code, electronic, or similar verification process shall require an initial quality assurance validation followed by ongoing quality assurance reviews at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.
  - 3. When a bar code verification, electronic verification, or similar verification process is utilized as specified in this Paragraph and in the absence of any human intervention in the product selection process, the stocking and restocking functions in systems located either on-site or off-site may be performed by a pharmacy technician without the necessity of direct pharmacist supervision.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended LR

...

#### Chapter 15. Hospital Pharmacy

...

#### **§1509. Drug Distribution Control**

- A. ...
- B. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of Chapter 12 – Automated Medication Systems of the board’s rules.
  - 1. When the pharmacy uses an electronic product verification process as described in §1217 of the board’s rules, and in the absence of any subsequent human intervention in the automated drug product selection process, the pharmacist-in-charge may elect to forego manual checks of drug products selected in that manner, provided however, that such election by the pharmacist-in-charge shall require an initial quality assurance validation followed by an ongoing quality assurance reviews at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.
  - 2. The pharmacist-in-charge remains accountable to the board for the accuracy of all drug distribution activities.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, 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.

The requirement to verify drug products dispensed by a pharmacy is still the same; the proposed rule allows – but does not mandate – the use of bar codes or other electronic product verification processes in lieu of manual product checks by the pharmacist.

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, the use of electronic technology to replace manual tasks.

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 Thursday, June 25, 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 rule, in increments of \$1,000, in FY 15 and the final rule in FY 16. The proposed rule authorizes pharmacies to use properly verified electronic technology to replace the manual checking of medications by pharmacists.

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 using automated medication systems (AMS). The current rules require pharmacists to manually check all medications packaged and prepared for delivery to patients as well as those medications placed in AMS for retrieval by nurses in hospitals, nursing homes, and other health care facilities. The proposed rule will authorize pharmacies to use bar code verification or other similar electronic product verification to substitute for the manual product checking by a pharmacist, as long as the electronic verification is subjected to an initial and ongoing quality assurance validation process. The time saved by pharmacists using such technology can be re-directed to other critical functions, including patient care activities.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will not have any effect on competition or employment.

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 Product Verification**  
**Baton Rouge, LA 70809** Effective Date of Rule: **August 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 rule, in increments of \$1,000, in FY 15 and the final rule in FY 16. The proposed rule authorizes pharmacies to use properly verified electronic technology to replace the manual checking of medications by pharmacists.

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 using automated medication systems (AMS). The current rules require pharmacists to manually check all medications packaged and prepared for delivery to patients as well as those medications placed in AMS for retrieval by nurses in hospitals, nursing homes, and other health care facilities. The proposed rule will authorize pharmacies to use bar code verification or other similar electronic product verification to substitute for the manual product checking by a pharmacist, as long as the electronic verification is subjected to an initial and ongoing quality assurance validation process. The time saved by pharmacists using such technology can be re-directed to other critical functions, including patient care activities.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will not have any effect on competition or employment.

Malcolm Broussard  
Signature of Agency Head or Designee

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

May 5, 2015  
Date of Signature

Evan Brasseur, Staff Director  
Legislative Fiscal Officer or Designee

5/6/15  
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 12 – Automated Medication Systems* as well as *Chapter 15 – Hospital Pharmacy* of its rules, specifically §1217 and §1509, to authorize the use of properly validated electronic product verification as a substitute for manual product checking by pharmacists. 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.

Stakeholders have suggested the rule requiring manual product checks by pharmacists may no longer be critical, due to two factors: some of the drug products are now unit-dosed packaged into opaque packages, which prohibit verification of color, markings, or other characteristics used by pharmacists to verify a drug product, and further, most drug product packaging now have bar codes which can be read with simple bar code readers to verify the contents of the package. The time required for manual product verification by pharmacist can be better used for other critical functions, including patient care activities.

- 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, \$1,000 each in FY 15 and FY 16. 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 1,935 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.

Pharmacies wishing to use electronic product verification as a substitute for manual product checking by pharmacists will need to perform an initial quality assurance validation of their electronic system and then repeat that assessment on a quarterly basis. The time required for the quality assurance validation will vary by the complexity of the system used by the facility.

- (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 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 1,000	\$ 1,000	\$ 0
PROFESSIONAL SERVICES	\$ 0	\$ 0	\$ 0
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 1,000</b>	<b>\$ 1,000</b>	<b>\$ 0</b>
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 \$1,000 for the printing of the Notice of Intent in the current fiscal year and the same amount for the printing of the Final Rule in the next fiscal year.

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

<u>SOURCE</u>	<u>FY 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 1,000	\$ 1,000	\$ 0
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 1,000</b>	<b>\$ 1,000</b>	<b>\$ 0</b>

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.

The proposed rule will have no impact on local governmental units.

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

N/A.

**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 14-15</u>	<u>FY 15-16</u>	<u>FY 16-17</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
<b>TOTAL</b>	<b>\$ 0</b>	<b>\$ 0</b>	<b>\$ 0</b>

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 directly affects those pharmacies using automated medication systems as well as hospital pharmacies using robotic dispensing systems. As part of the quality assurance process for those systems, the users typically measure the accuracy of the system on a continual basis. The stakeholders have suggested the continuing documented accuracy of electronic product verification is at least as accurate as manual product checking by pharmacists, if not more so, especially since some medications are now packaged in opaque packaging which prevents the pharmacist from visualizing color, shapes, size, and special markings that pharmacists use to verify drug products.

The proposed rule would allow, but not mandate, pharmacies using automated medication systems to rely on bar codes and other electronic product verification processes in lieu of manual product checking by pharmacists, but only when the quality assurance validation process is maintained on a quarterly basis. Stakeholders have suggested the time saved by the pharmacist previously performing manual product checks could be re-directed to other critical functions, including patient care activities.

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 not have any impact on receipts or revenue.

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 not have any effect on competition or employment.



\_\_\_\_\_  
Signature of Agency Head or Designee

**Malcolm J Broussard, Executive Director**

\_\_\_\_\_  
Typed Name and Title of Agency Head or Designee

**May 5, 2015**

\_\_\_\_\_  
Date of Signature