Louisiana Board of Pharmacy

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June 29, 2015

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

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

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for *Regulatory Project 2015-3 ~ Electronic Product Verification*

Dear Senator Alario:

As we indicated in our first report to you on May 7, 2015, the Board is currently amending 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. Subsequent to our Notice of Intent published in the May 20, 2015 edition of the *Louisiana Register*, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on June 25, 2015.

We received no public comments or testimony concerning the proposed rule prior to or during the public hearing. The Board has determined no revisions are necessary to the proposed rule as originally published, and further, determined it appropriate to move forward with the proposed rule.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the May 2015 *Louisiana Register*
- Summary of Comments from June 25, 2015 Public Hearing
- Full text of proposed rule

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rule as a Final Rule in the August 20, 2015 edition of the *Louisiana Register*. If you have any questions about the enclosed information or our procedures, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-HW@legis.la.gov
Editor, *Louisiana Register* – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health and Hospitals
Board of Pharmacy

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

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend §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.

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 26:1273 (June 2000), effective July 1, 2000, amended LR 41:

Chapter 15. Hospital Pharmacy

§1509. Drug Distribution Control

A. - A.3.e.iii. ...

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 40:2257 (November 2014), effective January 1, 2015, LR 41:

Family Impact Statement

In accordance with section 953 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the *Louisiana Register* with the proposed agency Rule.

1. The effect on the stability of the family. We anticipate no effect on the stability of the family.

2. The effect on the authority and rights of parents regarding the education and supervision of their children. We anticipate no effect on the authority and rights of parents regarding the education and supervision of their children.

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

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

5. The effect on the behavior and personal responsibility of children. We anticipate no effect on the behavior and personal responsibility of children.

6. The ability of the family or a local government to perform the function as contained in the proposed Rule. We anticipate no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with section 973 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

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

2. The effect on early childhood development and preschool through postsecondary education development. We anticipate no impact early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. We anticipate no positive impact on employment and workforce development.

4. The effect on taxes and tax credits. We anticipate no impact on taxes or tax credits.

5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. We anticipate no effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Statement

In accordance with section 965 of title 49 of the *Louisiana Revised Statutes*, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses.

1. The establishment of less stringent compliance or reporting requirements for small businesses. The 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.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. There are no reporting deadlines in the proposed Rule.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no reporting requirements in the proposed Rule.

4. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed Rule. The proposed Rule allows, but does not require, the use of electronic technology to replace manual tasks.

5. The exemption of small businesses from all or any part of the requirements contained in the proposed Rule. There are no exemptions for small businesses.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities.

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. We anticipate no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

2. The total direct and indirect effect on the cost to the provider to provide the same level of service. We anticipate minimal costs to the provider to implement the requirements of the proposed Rule.

3. The overall effect on the ability of the provider to provide the same level of service. We anticipate no effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Thursday, June 25, 2015 at 9 a.m. in the board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12 noon that same day.

Malcolm J. Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Electronic Product Verification

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

The proposed rule will result in a cost of approximately $2,000 for printing costs of the proposed 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 NONGOVERNMENTAL 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 J. Broussard
Executive Director
1505#017

Evan Brasseaux
Staff Director
Legislative Fiscal Office

Louisiana Board of Pharmacy

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Summary of Testimony & Public Comments
re
Regulatory Project 2015-3 ~ Electronic Product Verification
at
June 25, 2015 Public Hearing

There were no comments received prior to or during the public hearing.

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

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§1509. Drug Distribution Control

A. – A.3.e.iii. …

A. 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

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