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

November 18, 2014

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 2014-5 ~ Prescriptions*

Dear Senator Alario:

As we indicated in our first report to you on June 9, 2014, the Board is currently amending its rules to update the requirements for prescription forms and to codify contemporary practice standards for the minimum data set for prescriptions. Subsequent to our Notice of Intent published in the June 20, 2014 edition of the *Louisiana Register*, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on July 28, 2014.

We received no written comments or testimony prior to or during the hearing; however, shortly after the hearing, we received two requests for changes from one commentator. The Board considered those comments during their subsequent meeting on August 6. During that meeting, the Board directed staff how to respond to the commentators, and further, agreed to make some of the changes requested by the commentator. The Board sought and received an opinion from the Legislative Fiscal Office that the proposed revisions would not alter their original analysis as published in their original Fiscal & Economic Impact Statement. We then published a Potpourri Notice in the September 20, 2014 edition of the *Louisiana Register*. In accordance with the Administrative Procedures Act, we conducted a second public hearing on the proposed revisions at the Board office on October 30, 2014.

We received no written comments or testimony prior to or during the second public hearing. There were no concerns, objections, or requests for further changes. The Board considered the absence of such requests during their subsequent meeting on November 13, and further, determined it appropriate to move forward with the proposed rule as revised.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the June 2014 *Louisiana Register*
- Summary of Comments at July 28, 2014 Public Hearing
- Board Response to Commentator from April 29, 2014 Public Hearing
- Interim Opinion from Legislative Fiscal Office on September 8, 2014
- Potpourri Notice, as published in the September 2014 *Louisiana Register*
- Summary of Comments at October 30, 2014 Public Hearing
- Full text of proposed rule as revised

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the proposed rule, as revised, as a Final Rule in the January 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 Broussard

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-H&W@legis.la.gov
Editor, *Louisiana Register* – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health and Hospitals
Board of Pharmacy

Prescriptions (LAC 46:LIII.2511)

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 §2511, Prescriptions of its rules. The proposed Rule is intended to update the requirements for prescription forms and to codify contemporary practice standards for the minimum data set for prescriptions.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 25. Prescriptions, Drugs, and Devices
Subchapter B. Prescriptions
§2511. Prescriptions

A. ...

* * *

B. Requirements. A prescription shall contain the following data elements:

1. prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;

2. patient's name, and if for a controlled substance, address;

3. date prescription issued by the prescriber;

4. name of drug or device, and if applicable, strength, and quantity to be dispensed;

5. directions for use;

6. signature of prescriber; and

7. refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.

C. Written Prescriptions. A written prescription shall conform to the following format.

1. The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a single printed signature line.

2. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and, if for a controlled substance, the Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling the authorizing prescriber's printed name.

3. No prescription form shall contain more than four prescription drug orders. Each prescription drug order recorded on the form shall provide the following:

a. check box labeled "Dispense as Written", or "DAW", or both; and

b. the number of refills, if any.

4. The prescription shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner on the date issued and in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Examples of invalid signatures include rubber stamps, signatures of anyone other than the prescriber, and computer generated signatures.

5. Facsimile Prescription

a. The receiving facsimile machine of a prescription transmitted by facsimile shall be located within the pharmacy department.

b. The prescription transmitted by facsimile shall be on a non-fading legible medium.

c. All requirements applicable to written prescriptions in this Subsection shall apply to facsimile prescriptions, except Subparagraph B.7.c.

6. Forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.

7. Equivalent Drug Product Interchange

a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product provided the patient has been informed of, and has consented to, the proposed cost saving interchange.

b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written" or "DAW" or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.

c. For prescriptions reimbursable by Medicaid, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary" or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

D. Oral Prescriptions

1. Upon receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system. In the event a pharmacy intern or pharmacy technicians transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.

2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.

3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

E. Electronic Prescriptions

1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, DEA registration number.

2. The pharmacist shall not select an equivalent drug product when the prescriber indicates in the check box labeled "Dispense as Written" or "DAW" or both, and electronically transmits his signature on the formatted single signature line. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

F. Exclusion. The provisions of this Section shall not apply to medical orders written for patients in facilities licensed by the Department of Health and Hospitals or its successor.

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 29:2102 (October 2003), effective January 1, 2004, LR 40:

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 impact on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

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. To the extent a pharmacy provides services to individuals with developmental disabilities, and in the event the pharmacy receives a prescription that is incomplete according to the minimum data set identified in the proposed amendment, then one of the pharmacy's credentialed staff members may need to contact the prescriber of the prescription to obtain the missing information. That could require additional time which would have an indirect cost.

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.

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. There are no reporting requirements in the proposed Rule, but there is an allowance for the pharmacist to bypass the recording of verbal prescriptions on paper forms before entering the data into the pharmacy's information system.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. There are no schedules or deadlines or reporting requirements 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. There are no design standards in the proposed Rule. As noted above, there is an allowance for pharmacists to bypass the written recording of verbal prescription information prior to the data entry of that prescription information.

5. The exemption of small businesses from all or any part of the requirements contained in the proposed Rule. There are exemptions for those pharmacies located within hospitals or other facilities licensed by the Dept. of Health and Hospitals.

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 Monday, July 28, 2014 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: Prescriptions

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

The proposed rule changes will result in a cost of approximately $1,500 for printing costs of the proposed and final rules in FY 15. The proposed rule changes amend and clarify requirements for pharmacists regarding prescriptions transmitted in writing, orally or by electronic means.

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 changes.

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

The proposed rule changes directly affect pharmacists and pharmacies in how they receive, evaluate and process prescriptions. There are no significant estimated costs or economic benefits to pharmacists or pharmacies, though the proposed rule changes may provide a potential for some level of efficiency for the processing of verbal prescriptions. Additionally, the rule may indirectly affect certain prescribers in the information they include on their forms or how they sign their written prescription forms.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Malcolm J. Broussard
Executive Director
1406#024

Evan Brasseaux
Staff Director
Legislative Fiscal Office

Louisiana Board of Pharmacy

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Summary of Testimony & Public Comments
re
Regulatory Project 2014-5 ~ Prescriptions
at
July 28, 2014 Public Hearing

During the comment period identified in the Notice of Intent – June 20 through 12 noon on July 28 – the Board received no comments via mail, fax, or email. Further, no one appeared during the public hearing; therefore, no testimony was offered in response to the Board's public notice. Approximately two hours after the deadline, we received one comment letter via email. Although it was received after the deadline, the letter is included here for your consideration.

1. Mary Staples, on behalf of the National Association of Chain Drug Stores (NACDS)

With respect to §2511.C.4 [beginning on Line 42], the commentator requested consideration of permitting electronic signatures on written prescription forms.

With respect to §2511.E.2 [beginning on Line 91], the commentator requested consideration of alternative language for the instruction to prohibit generic interchange on electronic prescriptions.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 28, 2014

Mr. Malcolm J. Broussard
Executive Director
Louisiana Board of Pharmacy
Department of Health & Hospitals
P. O. Box 91030
Baton Rouge, LA 70821

RE: Regulatory Project 2014-5-Prescriptions

Dear Mr. Broussard:

On behalf of the 16 chain companies operating in the state of Louisiana, the National Association of Chain Drug Stores (NACDS) is writing to submit comments on the Board of Pharmacy's ("the Board") proposed changes to Section 2511 of Title 46 of the Louisiana Administrative Code. These proposed changes would update the requirements for prescription forms and codify practice standards for the minimum data that is required on each prescription.

Specifically, NACDS and its members have concerns with the proposed changes to the following sections:

Section 2511(C)(4)-Rx Signatures
As written, the proposed changes would require prescriptions to be manually signed by the practitioner on the date that the prescription was issued. Currently, computer generated signatures are acceptable for faxed and other electronically transmitted prescriptions. In addition, under federal law, a prescriber's electronic signature or other authorized secure method of validation can be provided with prescriptions that are transmitted electronically and can serve as a valid signature on such prescriptions. In an effort to align state rules with federally accepted requirements we urge the Board to make the following changes to the proposed language:

> *(C)(4) The prescription shall be written with ink or indelible pencil, typewritten, or printed on a computer and shall be signed by the practitioner on the date issued and in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). In the event of an electronic prescription, a prescriber's electronic signature or other authorized secure method of validation shall be provided and shall serve as a valid signature. Examples of invalid signatures include rubber stamps~~,~~ and signatures of anyone other than the prescriber ~~and computer generated signatures~~.*

Section 2511(E)(2)-Electronic Prescriptions
While the Board is not proposing any changes to this section we would like to take this opportunity to point out some areas of concern, as well as make some suggested changes for review. The current language states that "pharmacists shall not select an equivalent drug

product when the prescriber indicates in the check box labeled "Dispense as Written" or "DAW" or both, and electronically transmits his signature on the formatted single signature line." When electronic prescriptions are generated there is no DAW checkbox or formatted signature line that can be used. Instead, in instances where the prescribing physician requires that a branded product is use the electronic prescription will include verbiage that states "Dispense as Written" or "Brand Medically Necessary". Being that this is the case, we ask the board to review the current language and consider the following suggestion:

> *(E)(2) The pharmacist shall not select an equivalent drug product when the prescriber indicates ~~in the check box labeled~~ "Dispense as Written" or ~~"DAW"~~ "Brand Medically Necessary" or both, and ~~electronically~~ transmits his electronic signature or other authorized secure method of validation ~~on the formatted single signature line.~~ Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.*

We appreciate the opportunity to submit comments on these issues and we look forward to working with the Board as they finalize and implement these changes.

Sincerely,

Mary Staples

Mary Staples
Director, Government Affairs

cc: Nick Cahanin, The Picard Group

Louisiana Board of Pharmacy

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Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
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August 20, 2014

Mary Staples
Director, Government Affairs
National Association of Chain Drug Stores
1560 East Southlake Blvd Ste 230
Southlake, TX 76092

Via E-mail: MStaples@nacds.org

Electronic Mail – Delivery Receipt Requested

Re: *Regulatory Project 2014-5 ~ Prescriptions*

Dear Ms. Staples:

Thank you for taking the time to review the Board's proposed rule changes relative to prescription forms and then prepare and submit comments in response thereto. The Board considered your comments during their last meeting on August 6, and they have directed me to respond to your comments as follows:

With respect to §2511.C.4, you requested the Board consider the insertion of an additional sentence recognizing an electronic signature or other authorized secure method of validation, and you also requested the deletion of the final four words of that sentence.

Response: Paragraph C of §2511 discusses written prescription forms; electronic prescription forms are discussed in Paragraph E of this same section. The Board took notice of the federal Drug Enforcement Administration (DEA) rule requiring manual signatures for prescriptions for controlled substances, even for those prescriptions generated by computer and then sent by electronic facsimile [21 CFR 1306.05(d)]. The Board expressed their concern for potential confusion over different rules for prescriptions for controlled substances and non-controlled substances. The Board opted for consistency in the signature requirements regardless of the medication prescribed. The Board voted unanimously to retain the language of the original proposal.

With respect to §2511.E.2, you requested the Board consider several amendments, including deletion of the reference to the check box, deletion of the abbreviation "DAW", insertion of the words "Brand medically necessary", insertion of the phrase "electronic signature or other authorized secure method of validation", as well as deletion of the reference to a formatted single signature line.

Response: The Board was receptive to most of your suggestions in this section of the proposed rule. They agreed to remove the reference to the check box, decided to retain the abbreviation "DAW", agreed to add the words "Brand medically necessary", agreed to remove the reference to the formatted single signature line, and agreed to inserting a reference to an electronic signature, but did not agree with your reference to "or other authorized secure method of valuation." The Board took note of the requirement for the practitioner's signature and indicated their intent – at this time – to not attempt to define what a signature was or was not, so as to not impede technology. Some of the members expressed concern that the phrase "or other authorized secure method of validation" seemed to inject some uncertainty over what that might mean.

Since the Board has recommended a revision to the original proposal, we are required to conduct another public hearing to receive comments on the recommended changes. Please monitor our rulemaking notices for the scheduling of that public hearing. Again, thank you for your interest and participation in the Board's rulemaking activities.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

Malcolm J. Broussard

From: Boxberger, Alan [boxbergera@legis.la.gov]
Sent: Monday, September 08, 2014 1:08 PM
To: Catherine Brindley
Cc: Malcolm J. Broussard
Subject: FW: Pharmacy Board - Regulatory Project 2014-5 ~ Prescriptions
Attachments: 2014-5_LFO-ReviewRequest_2014-0820.doc; 2014-5_FEIS-Final-S.pdf; 2014-5 _PotpurriNotice-for-OSR_2014-0920.doc

Catherine,

The Fiscal Office has reviewed proposed changes to a proposed rule change originally submitted to The Register in June of 2014, and clarifies requirements for pharmacists regarding prescriptions transmitted in writing, orally or by electronic means.

The Fiscal Office confirms that the changes, as proposed in the attached document, do not alter the analysis included in the original fiscal and economic impact statement.

Please let me know if you require additional information or if you have questions.

Thank You,

Alan M. Boxberger
Legislative Fiscal Analyst
LA Legislative Fiscal Office
225-342-7164

From: "Malcolm J. Broussard" <mbroussard@pharmacy.la.gov>
Date: Wednesday, August 20, 2014 at 3:31 PM
To: "Boxberger, Alan" <boxbergera@legis.la.gov>
Cc: "Pedersen, Jean" <pedersej@legis.la.gov>
Subject: Pharmacy Board - Regulatory Project 2014-5 ~ Prescriptions

Hi Alan,

With respect to this project, the Board published its *Notice of Intent* in the June 2014 edition of the ***Louisiana Register*** and then conducted its public hearing on July 28. During the Board's subsequent meeting on August 6, the members considered the one written comment received at the hearing. Of the two requests made by the commentator, the Board agreed with one of them and has agreed to recommend the revision of the original proposal as requested.

The Board does not believe the recommended revisions will materially affect the stakeholders, and further, that no revision to the fiscal impact statement is necessary. We seek your analysis and concurrence before moving forward.

Attached to this message you should find the following documents:

- Memo requesting your review
- Scanned copy of original signed fiscal impact statement
- Proposed *Potpourri Notice* for the September 2014 edition of the ***Louisiana Register***

Please let me know if you have any questions or need additional information.

Thanks,
Malcolm

Malcolm J Broussard
Executive Director
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MEMORANDUM

To: Alan Boxberger
Legislative Fiscal Office

From: Malcolm Broussard

Date: August 20, 2014

Re: Request for Review of Impact on Signed Fiscal Note
From Suggested Revision of Original Notice of Intent

With respect to our *Regulatory Project 2014-5 ~ Prescriptions*, our fiscal note was ultimately approved on June 5, 2014. I have attached a copy of that document for your reference, along with a copy of the original proposal. As indicated in the Notice of Intent, the proposal seeks to amend §2511 of the Board's rules relative to prescription forms. The rules addresses the three different media of contemporary prescriptions – oral, written, and electronic.

During the public hearing held by the Board on July 28, the Board received comments requesting consideration of what the Board considered to be minor changes in the portion of the rule relative to electronic prescriptions. The Board agreed with most of the suggested changes and will recommend the requested revisions of the original proposal. We do not believe the requested changes will have any material impact on the stakeholders, but wanted to solicit your opinion before moving forward. Please let me know if you need any additional information, and thank you for your review.

Potpourri Notice

Department of Health and Hospitals
Board of Pharmacy

Prescriptions (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 Board of Pharmacy published its Notice of Intent in the June 2014 edition of the Louisiana Register, specifying its proposal to amend §2511 of its rules to update the requirements for prescription forms and to codify contemporary practice standards for the minimum data set for prescriptions. As indicated in the notice, the Board conducted a public hearing on July 28 to receive comments and testimony on the proposal.

During the Board's consideration of those comments and testimony at its subsequent meeting on August 6, they agreed with a request to revise the original proposal by amending Paragraph E relative to electronic prescription forms, more specifically by deleting the references to a check box and a formatted single signature line as well as by adding an additional phrase prohibiting generic interchange. The proposed revision is noted below.

The Legislative Fiscal Office has evaluated the impact of the proposed revisions of the original proposal and has opined the suggested revisions would not adversely increase any cost to the stakeholders.

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 as well as these proposed revisions to the original proposal. A public hearing on these proposed revisions to the original proposal is scheduled for Thursday, October 30, 2014 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 25. Prescriptions, Drugs, and Devices

...

Subchapter B. Prescriptions

§2511. Prescriptions

A. – D. ...

E. Electronic Prescriptions

1. ...

2. The pharmacist shall not select an equivalent drug product when the prescriber indicates "Dispense as Written", "DAW" or "Brand Medically Necessary" and transmits his electronic signature. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

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 40:

POTPOURRI

Department of Health and Hospitals
Board of Pharmacy

Prescriptions (LAC 46:LIII.2511)

Editor's Note: The following Potpourri document was omitted from a scheduled September 20, 2014 publication date in the *Louisiana Register* due to a production error. The Potpourri document addresses proposed revisions to a June 20, 2014 Notice of Intent, *Louisiana Register*, pages 1200-1202, and subsequent public hearings. An October 30, 2014 final public hearing is scheduled herewith.

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 Board of Pharmacy published its Notice of Intent in the June 2014 edition of the Louisiana Register, specifying its proposal to amend §2511 of its rules to update the requirements for prescription forms and to codify contemporary practice standards for the minimum data set for prescriptions. As indicated in the notice, the Board conducted a public hearing on July 28 to receive comments and testimony on the proposal.

During the Board's consideration of those comments and testimony at its subsequent meeting on August 6, they agreed with a request to revise the original proposal by amending Paragraph E relative to electronic prescription forms, more specifically by deleting the references to a check box and a formatted single signature line as well as by adding an additional phrase prohibiting generic interchange. The proposed revision is noted below.

The Legislative Fiscal Office has evaluated the impact of the proposed revisions of the original proposal and has opined the suggested revisions would not adversely increase any cost to the stakeholders.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 25. Prescriptions, Drugs, and Devices
Subchapter B. Prescriptions
§2511. Prescriptions

A. - D. ...

E. Electronic Prescriptions

1. ...

2.. The pharmacist shall not select an equivalent drug product when the prescriber indicates "Dispense as Written", "DAW" or "Brand Medically Necessary" and transmits his electronic signature. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

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:

Public Comments

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 as well as these proposed revisions to the original proposal.

Public Hearing

A public hearing on these proposed revisions to the original proposal is scheduled for Thursday, October 30, 2014 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

1410#017

Louisiana Board of Pharmacy

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Summary of Testimony & Public Comments
re
Regulatory Project 2014-5 ~ Prescriptions
at
October 30, 2014 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 25. Prescriptions, Drugs, and Devices

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Subchapter B. Prescriptions

§2511. Prescriptions

A. …

B. Requirements. A prescription shall contain the following data elements:

1. Prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;
2. Patient's name, and if for a controlled substance, address;
3. Date prescription issued by the prescriber;
4. Name of drug or device, and if applicable, strength**,** and quantity to be dispensed;
5. Directions for use;
6. Signature of prescriber; and
7. Refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.

C. Written Prescriptions. A written prescription shall conform to the following format:

1. The prescription form shall be of a size not less than four inches by five inches, and shall bear a single printed signature line.
2. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and, if for a controlled substance, the Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling the authorizing prescriber's printed name.
3. No prescription form shall contain more than four prescription drug orders. Each prescription drug order recorded on the form shall provide the following:
    a. Check box labeled "Dispense as Written", or "DAW", or both; and
    b. The number of refills, if any.
4. The prescription shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner on the date issued and in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith. Examples of invalid signatures include rubber stamps, signatures of anyone other than

the prescriber, and computer generated signatures.

5. Facsimile Prescription.
    a. The receiving facsimile machine of a prescription transmitted by facsimile shall be located within the pharmacy department.
    b. The prescription transmitted by facsimile shall be on a non-fading legible medium.
    c. All requirements applicable to written prescriptions in this Subsection shall apply to facsimile prescriptions, except Subsection (B)(7)(c).
6. Forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.
7. Equivalent Drug Product Interchange
    a. The pharmacist shall not select an equivalent drug product when the prescriber handwrites a mark in the check box labeled "Dispense as Written", or "DAW", or both, and personally handwrites his signature on a printed single signature line. Otherwise, the pharmacist may select an equivalent drug product provided the patient has been informed of, and has consented to, the proposed cost saving interchange.
    b. In the event an authorized prescriber has indicated that an equivalent drug product interchange is prohibited by handwriting a mark in the check box labeled "Dispense as Written" or "DAW" or both, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.
    c. For prescriptions reimbursable by Medicaid, the authorized prescriber may only prohibit equivalent drug product interchange by handwriting the words "brand necessary' or "brand medically necessary" on the face of the prescription order or on a sheet attached to the prescription order.

D. Oral Prescriptions

1. Upon receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system. In the event a pharmacy intern or pharmacy technicians transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.
2. The pharmacist shall not select an equivalent drug product when the authorized prescriber or his agent has verbally indicated a specific brand name drug or product is ordered.
3. The pharmacist may select an equivalent drug product if the authorized prescriber or his agent has given his approval to the equivalent drug product interchange. The patient shall be informed of, and consent to, the proposed cost saving interchange.

E. Electronic Prescriptions

1. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, DEA registration number.
2. The pharmacist shall not select an equivalent drug product when the prescriber indicates "Dispense as Written", "DAW" or "Brand Medically Necessary" and transmits his electronic signature. Otherwise, the pharmacist may select an equivalent drug product, provided the patient has been informed of, and consents to, the proposed cost saving interchange.

F. Exclusion. The provisions of this Section shall not apply to medical orders written for patients in facilities licensed by the Department of Health and Hospitals or its successor.

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: