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

April 10, 2017

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 2017-2 ~ Equivalent Drug Product Interchange

Dear Senator Alario:

The Board has initiated the rulemaking process to amend its rules relative to equivalent drug product interchange, as required by Act 391 of the 2015 Regular Legislative Session. The proposed rule will require pharmacists dispensing certain interchangeable biological products to communicate certain information about the product dispensed to the prescribing practitioner. 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
- Act 391 of 2015 Regular Legislative Session

As indicated in the solicitation, we will convene a public hearing on May 30, 2017 to receive public comments and testimony on this proposed rule change. 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 Broussard

Malcolm J Broussard
Executive Director

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

Notice of Intent

Department of Health
Board of Pharmacy

Equivalent Drug Product Interchange (LAC 46:LIII.2511 and 2517)

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 and §2517 of its rules. The amended rules will implement Act 391 of the 2015 Legislature, which amended the statutory definition of the term 'equivalent drug product' and imposed certain communication requirements on pharmacists dispensing certain interchangeable biological products.

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.6. …

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 or Medicare, 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 the 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 technician 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, the 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 41:98 (January 2015), amended LR 41:2147 (October 2015), amended LR

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§2517. Prescription Dispensing

A – A.6 …

B. Equivalent Drug Product Interchange

1. The pharmacist shall not select an equivalent drug product when the prescriber prohibits interchange by any one of the following methods:
    a. On a prescription generated in written form, the prescriber shall handwrite a mark in a check box labeled "Dispense as Written", or the abbreviation "DAW", or both, and shall manually sign the prescription form.
        1. For prescriptions reimbursable by the state Medicaid program, the prescriber shall handwrite the words "Brand Necessary" or "Brand Medically Necessary" on the prescription form or on a sheet of paper attached to the prescription form.
    b. On a prescription generated in oral or verbal form, the prescriber (or the prescriber's agent) shall indicate a specific brand name drug or product is ordered by the practitioner, and the pharmacist shall note such information on the file copy of the prescription.
    c. On a prescription generated in electronic form, the prescriber shall indicate "Dispense as Written", "DAW", or "Brand Medically Necessary."
2. Where the prescriber has indicated that an equivalent drug product interchange is prohibited, 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.
3. In the event the prescriber has not prohibited equivalent drug product interchange in the manner described above, the pharmacist may select an equivalent drug product for dispensing, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.
4. When the pharmacist selects a biological product rated as interchangeable for the product ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to the prescriber – by any means, but no later than five business days following the dispensing date – the specific product dispensed to the patient, including the name of the product and the manufacturer. However, no such communication to the prescriber is required when:
    a. The prescriber prohibited interchange in the manner described above;
    b. There is no product rated as interchangeable or therapeutically equivalent; or
    c. The product dispensed is a refill not changed from the product dispensed on the prior filling of the prescription.

~~B.~~ C. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.

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 29:2104 (October 2003), effective January 1, 2004, amended LR

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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.

The proposed rule will have 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.

The proposed rule will have 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.

The proposed rule will have no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

The proposed rule will have no effect on family earnings or family budget.

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

The proposed rule will have 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.

The proposed rule will have 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.

The proposed rule will have no effect on household income, assets, or financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

The proposed rule will have no effect on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

The proposed rule will have no effect on employment or workforce development.

IV. The effect on taxes and tax credits.

The proposed rule will have no effect on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

The proposed rule will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

PROVIDER IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

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

I. The effect on the staffing level requirements or qualifications required to provide the same level of service.

The proposed rule will have 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.

The proposed rule will have no effect on the total direct or indirect costs to the provider to provide the same level of service.

III. The overall effect on the ability of the provider to provide the same level of service.

The proposed rule will have no effect on the ability of the provider to provide the same level of service.

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

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

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

The proposed rule requires the dispensing pharmacist to communicate certain information to a prescriber within five days, but allows that communication to be completed in any manner; there are no reporting requirements in the proposed rule.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The five day deadline for the required communication was imposed in the enabling legislation; therefore, the rule cannot allow for a less stringent schedule.

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.

There are no design or operational standards required in the propose rule.

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.

SOLICITATION OF 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. A public hearing on this proposed rule is scheduled for Tuesday, May 30, 2017 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)

Other than the publication fee associated with the proposed rule changes, which are estimated to cost the Board of Pharmacy $2,000, it is not anticipated that state or local governmental units will incur any other costs or savings. The proposed rule codifies Act 391 of the 2015 Regular Legislative Session and revises the definition of equivalent drug products and imposes communication requirements on pharmacists dispensing certain interchangeable biological products.

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

The proposed rule change will not affect state or local government revenue collections.

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

The proposed rule imposes certain communication requirements on pharmacists dispensing certain interchangeable biological products within five days of dispensing the product, but permits that communication to the prescriber to be accomplished by any means. Therefore, the cost of the communication is anticipated to be minimal.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will have no effect on competition or employment as it only adds a reporting requirement if certain interchangeable biological products are dispensed.

ENROLLED

2015 Regular Session

ACT No. 391

HOUSE BILL NO. 319

BY REPRESENTATIVE SIMON

AN ACT

To amend and reenact R.S. 37:1164(16) and to enact R.S. 37:1164(58) and 1226.1, relative to interchangeable biological products; to provide for definitions; to provide for licensure penalties; to require certain information to be sent to a prescriber; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1164(16) is hereby amended and reenacted and R.S. 37:1164(58) and 1226.1 are hereby enacted to read as follows:

§1164. Definitions

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

* * *

(16) "Equivalent drug product" means either of the following:

(a) ~~a~~ A drug product that has been rated as a pharmaceutical equivalent by the ~~federal food and drug administration~~ United States Food and Drug Administration (FDA) and has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendial or other applicable standards such as strength, quality, purity, and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, excipients including colors, flavors, preservatives, and expiration time.

(b) A biological product that is either one of the following:

(1) Deemed by the United States Food and Drug Administration as meeting the standard set forth in 42 U.S.C. 262(k)(4) and rated as interchangeable in the *Lists of Licensed Biologic Products with Reference Product Exclusivity and Biosimilarity and Interchangeability Evaluations*, sometimes referred to as the "Purple Book", or its successors.

(2) Rated therapeutically equivalent by the United States Food and Drug Administration as set forth in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, sometimes referred to as the "Orange Book", or its successors.

* * *

(58) "Biological product" has the meaning assigned by Section 351 of the Public Health Service Act, 42 U.S.C. 262.

* * *

§1226.1. Communication to the prescriber

A. No later than five business days following the dispensing of a biological product, the dispensing pharmacist or his designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer.

B. The required communication included in Subsection A may be done by any means.

C. No communication shall be required if there is no interchangeable or therapeutically equivalent biological product approved by the United States Food and Drug Administration for the product prescribed, or if the prescription is a refill not changed from the product dispensed on the prior filling of the prescription.

D. Nothing in this Section shall create a cause of action against the prescriber and the dispensing pharmacist or his designee for a communication as required pursuant to this Section.

E. No communication shall be required pursuant to this Section if the prescriber indicates "dispense as written".

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____