

2015 Regular Session

HOUSE BILL NO. 319

BY REPRESENTATIVE SIMON

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

DRUGS/PRESCRIPTION: Provides relative to the dispensing of interchangeable biological products

1 AN ACT

2 To amend and reenact R.S. 37:1164(16) and 1241(A)(17) and to enact R.S. 37:1164(58) and  
3 (59), 1185, and 1226.1, relative to interchangeable biological products; to provide  
4 for definitions; to provide for licensure penalties; to require certain information to  
5 be sent to a prescriber; to require the posting of certain information on the Louisiana  
6 Board of Pharmacy's web page; and to provide for related matters.

7 Be it enacted by the Legislature of Louisiana:

8 Section 1. R.S. 37:1164(16) and 1241(A)(17) are hereby amended and reenacted and  
9 R.S. 37:1164(58) and (59), 1185, and 1226.1 are hereby enacted to read as follows:

10 §1164. Definitions

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

13 \* \* \*

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

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

1                    (b) An interchangeable biological product.

2   \*       \*       \*

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

5                    (59) "Interchangeable" means meeting the criteria contained in 42 U.S.C.  
6 262(k)(4) or having been deemed therapeutically equivalent by the United States  
7 Food and Drug Administration as set forth in the latest edition or supplement of the  
8 Approved Drug Products with Therapeutic Equivalence Evaluations prepared by the  
9 United States Food and Drug Administration and sometimes referred to as the  
10 "Orange Book".

11   \*       \*       \*

12                    §1185. Interchangeable biological products; list maintained on Louisiana Board of  
13 Pharmacy's web page

14                    The board shall maintain on its public web page a link to the current list, if  
15 available, of biological products determined by the United States Food and Drug  
16 Administration to be interchangeable.

17   \*       \*       \*

18                    §1226.1. Communication to the prescriber

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

23                    B.(1) The dispensing pharmacist or his designee shall convey the  
24 communication required by Subsection A of this Section by making an entry into an  
25 interoperable electronic medical records system, through an electronic prescribing  
26 technology, a pharmacy benefit management system, or a pharmacy record that can  
27 be accessed electronically by the prescriber. Entry into one of the methods of  
28 communication pursuant to this Paragraph is presumed to provide the required notice  
29 to the prescriber.

1                    (2) If the required communication cannot be conveyed pursuant to a method  
2                    listed in Paragraph (1) of this Subsection, the dispensing pharmacist or his designee  
3                    shall communicate the biological product dispensed to the prescriber using facsimile,  
4                    telephone, electronic transmission, or other prevailing means.

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

9                                    \*            \*            \*

10                   §1241. Refusal, restriction, suspension, or revocation of license

11                    A. The board may, after due notice and hearing, assess a fine not to exceed  
12                    the sum of five thousand dollars for each offense, refuse to license, register, certify,  
13                    or permit any applicant, refuse to renew the license or permit of any person, or may  
14                    revoke, summarily suspend, suspend, place on probation, reprimand, issue a warning  
15                    against the person who was issued the license, registration, certificate, permit, or any  
16                    other designation deemed necessary to engage in the practice of pharmacy upon  
17                    proof that the person:

18                                    \*            \*            \*

19                    (17)(a) Has knowingly selected an equivalent drug or interchangeable  
20                    biological product if the practitioner or authorized prescriber instructs otherwise by  
21                    either of the following:

22                    (i) On a written prescription drug order, handwriting a mark in a check-off  
23                    box labeled with "Dispense as Written", or the abbreviation "DAW", or both, and  
24                    personally handwriting his signature on a printed-single-signature line. A written  
25                    prescription drug order shall indicate the practitioner's or authorized prescriber's  
26                    name, licensure designation, and practice affiliation, if any.

27                    (ii) On an oral prescription, verbally indicating that a specific brand-name  
28                    drug or biological product is ordered by the practitioner or authorized prescriber or

1 his agent. The pharmacist shall note such information on the file copy of the  
2 prescription.

3 (b) The patient shall be informed of, and consent to, the equivalent drug or  
4 interchangeable biological product interchange when the practitioner or authorized  
5 prescriber permits the equivalent drug or interchangeable biological product  
6 interchange.

7 (c) In order to comply with 42 CFR 447.331, for prescriptions reimbursable  
8 by Medicaid, the practitioner or authorized prescriber may prohibit equivalent drug  
9 or interchangeable biological product interchange only by handwriting the words  
10 "brand medically necessary" or "brand necessary" directly on the written prescription  
11 drug order or on a sheet attached to the prescription. Recipients of Medicaid  
12 prescription benefits demonstrate implied consent by their participation in the  
13 program, provided the practitioner or authorized prescriber has not prohibited  
14 equivalent drug or interchangeable biological product interchange in the manner  
15 specified in Subparagraph (a) of this Paragraph.

16 \* \* \*

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DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

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**Abstract:** Prohibits the dispensing of an interchangeable biological product if the prescription requires the named product and requires notification to the prescriber when an interchangeable biological product is dispensed.

Proposed law defines "biological product", "equivalent drug product", and "interchangeable".

Proposed law requires the La. Board of Pharmacy to maintain on its public web page a link to the current list, if available, of biological products determined by the U.S. Food and Drug Administration (FDA) to be interchangeable.

Present law prohibits a pharmacist from knowingly dispensing an equivalent drug product if the prescriber instructs otherwise on the written prescription drug order or by verbally indicating the instruction for an oral prescription.

Proposed law retains present law and adds a prohibition against dispensing an interchangeable biological product if the prescriber instructs otherwise.

Present law requires the patient to consent to the equivalent drug if substitution is permitted by the prescriber.

Proposed law retains present law and adds the requirement that the patient consent to the interchangeable biological product if substitution is permitted by the prescriber.

Proposed law requires the dispensing pharmacist or his designee to communicate to the prescriber the specific biological product provided to the patient, including the name of the product and the manufacturer, no later than five days following the dispensing of a biological product unless there is no interchangeable biological product approved by the FDA for the product prescribed or a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

Proposed law requires the communication to be conveyed by making an entry into an interoperable electronic medical records system through an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record that can be accessed electronically by the prescriber.

Proposed law provides that entry into one of the methods of communication listed in proposed law is presumed to provide the required notice to the prescriber.

(Amends R.S. 37:1164(16) and 1241(A)(17); Adds R.S. 37:1164(58) and (59), 1185, and 1226.1)

#### Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Health and Welfare to the original bill:

1. Add a pharmacy benefit management system as a method of notification.
2. Provide that entry into one of the enumerated methods of communication is presumed to provide the required notice to the prescriber.