

**ACT No. 391**

2015 Regular Session

HOUSE BILL NO. 319

BY REPRESENTATIVE SIMON

1 AN ACT

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

6 Be it enacted by the Legislature of Louisiana:

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

9 §1164. Definitions

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

12 \* \* \*

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

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

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

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

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

11    \*            \*            \*

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

14    \*            \*            \*

15                    §1226.1. Communication to the prescriber

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

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

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

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

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

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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PRESIDENT OF THE SENATE

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_