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: _____