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

AN ACT

To amend and reenact R.S. 37:1164(16) and 1241(A)(17) and to enact R.S. 37:1164(58) and (59), 1185, 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; to require the posting of certain information on the Louisiana Board of Pharmacy's web page; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1164(16) and 1241(A)(17) are hereby amended and reenacted and R.S. 37:1164(58) and (59), 1185, 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 <u>either of the following:</u>

<u>(a)</u> ~~a~~ <u>A</u> drug product that has been rated as a pharmaceutical equivalent by the ~~federal food and drug administration~~ <u>United States Food and Drug Administration</u> (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) An interchangeable biological product.

* * *

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

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

* * *

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

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

* * *

§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.(1) The dispensing pharmacist or his designee shall convey the communication required by Subsection A of this Section by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber.

(2) If the required communication cannot be conveyed pursuant to a method listed in Paragraph (1) of this Subsection, the dispensing pharmacist or his designee

shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means.

C. No communication shall be required if there is no interchangeable 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.

* * *

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

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

* * *

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

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

(ii) On an oral prescription, verbally indicating that a specific brand-name drug or biological product is ordered by the practitioner or authorized prescriber or his agent. The pharmacist shall note such information on the file copy of the prescription.

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

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

* * *

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)]

HB 319 Original 2015 Regular Session Simon

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.

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