By Senator Grimsley

21-00224-13 2013732__

A bill to be entitled

An act relating to prescription drugs; providing definitions; authorizing a pharmacist to substitute a biosimilar product for a prescribed product if certain requirements are met; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. (1) As used in this section, the term:

(a) "Biological product" means a virus; therapeutic serum; toxin; antitoxin; vaccine; blood; blood component or derivative; allergenic product; protein, except any chemically synthesized polypeptide, or analogous product; arsphenamine or derivative of arsphenamine, or any other trivalent organic arsenic compound, which is used to prevent, treat, or cure a disease or condition of a human being.

(b) "Biosimilar" means that a biological product is highly similar to a prescribed product notwithstanding minor differences in clinically inactive components. There must not be any clinically meaningful differences between the biological product and the prescribed product with regard to the safety, purity, and potency of the product.

(c) "Interchangeable" means a biological product may be substituted for the prescribed product without the intervention of the prescriber.

(d) "Prescriber" means a practitioner licensed to prescribe medicinal drugs.

(2) A pharmacist may substitute a biosimilar product for a prescribed product if:

(a) The United States Food and Drug Administration has determined that the biosimilar product is interchangeable with the prescribed product for the specified, indicated use;

(b) The prescriber does not express in writing, verbally, or electronically a preference against the substitution;

(c) The person presenting the prescription is notified of the substitution in a manner consistent with the requirements of section 465.025(3), Florida Statutes;

(d) The pharmacist or pharmacist's agent notifies the prescriber or the prescriber's agent by facsimile, telephone, voicemail, e-mail, or other electronic means of the substitution within 10 business days after receiving the prescription; and

(e) The pharmacist and prescriber retain a written record of the biosimilar substitution for at least 4 years.

Section 2. This act shall take effect July 1, 2013.