**By** the Committee on Health Policy; and Senator Grimsley

588-03414A-13 2013732c1

A bill to be entitled

An act relating to pharmacy; amending s. 465.019, F.S.; permitting a class II institutional pharmacy formulary to include biologics, biosimilars, and biosimilar interchangeables; creating s. 465.0252, F.S.; providing definitions; providing requirements for a pharmacist to dispense a substitute biological product that is determined to be biosimilar to and interchangeable for the prescribed biological product; providing notification requirements for a pharmacist in a class II or modified class II institutional pharmacy; requiring the Board of Pharmacy to maintain a current list of interchangeable biosimilar products; providing an effective date.

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

Section 1. Subsection (6) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.—

(6) In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, ~~and~~ proprietary preparations, biological products, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards

of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

Section 2. Section 465.0252, Florida Statutes, is created to read:

465.0252 Substitution of interchangeable biosimilar products.—

(1) As used in this section, the terms "biological product," "biosimilar," and "interchangeable" have the same meanings as defined in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(2) A pharmacist may only dispense a substitute biological product for the prescribed biological product if:

(a) The United States Food and Drug Administration has determined that the substitute biological product is biosimilar to and interchangeable for the prescribed biological product.

(b) The practitioner ordering the prescription does not express a preference against substitution in writing, verbally, or electronically.

(c) The pharmacist notifies the person presenting the prescription of the substitution in the same manner as provided in s. 465.025(3)(a).

(d) The pharmacist or the pharmacist's agent, within 5 business days after dispensing the substitute biological product in lieu of the prescribed biological product, notifies the practitioner ordering the prescription of the substitution by facsimile, telephone, voicemail, e-mail, electronic medical record, or other electronic means.

(e) The pharmacist and the practitioner ordering the

prescription each retain a written or electronic record of the substitution for at least 2 years.

(3) A pharmacist who practices in a class II or modified class II institutional pharmacy shall comply with the notification provisions of paragraphs (2)(c) and (d) by entering the substitution in the institution's written medical record system or electronic medical record system.

(4) The board shall maintain on its public website a current list of biological products that the United States Food and Drug Administration has determined are biosimilar and interchangeable as provided in paragraph (2)(a).

Section 3. This act shall take effect July 1, 2013.