A bill to be entitled

An act relating to pharmacy; 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; 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. 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 specified indicated use of the prescribed biological product.

(b) The prescribing health care provider 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, within 10 business days after dispensing the substitute biological product in lieu of the prescribed biological product, notifies the prescribing health care provider of the substitution by facsimile, telephone, voicemail, e-mail, electronic medical record, or other electronic means.

(e) The pharmacist and the prescribing health care provider each retain a written record of the substitution for at least 4 years.

(3) 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 2. This act shall take effect July 1, 2013.