CS/HB 365

2013 A bill to be entitled 1 2 An act relating to pharmacy; creating s. 465.0252, 3 F.S.; providing definitions; providing requirements 4 for a pharmacist to dispense a substitute biological 5 product that is determined to be biosimilar to and 6 interchangeable for the prescribed biological product; 7 requiring the Board of Pharmacy to maintain a current 8 list of interchangeable biosimilar products; providing 9 an effective date. 10 11 Be It Enacted by the Legislature of the State of Florida: 12 13 Section 1. Section 465.0252, Florida Statutes, is created 14 to read: 15 465.0252 Substitution of interchangeable biosimilar 16 products.-17 (1) As used in this section, the terms "biological product," "biosimilar," and "interchangeable" have the same 18 meanings as defined in s. 351 of the federal Public Health 19 20 Service Act, 42 U.S.C. s. 262. 21 (2) A pharmacist may only dispense a substitute biological 22 product for the prescribed biological product if: 23 The United States Food and Drug Administration has (a) 24 determined that the substitute biological product is biosimilar 25 to and interchangeable for the specified indicated use of the 26 prescribed biological product. 27 The prescribing health care provider does not express (b) a preference against substitution in writing, verbally, or 28

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29	electronically.
30	(c) The pharmacist notifies the person presenting the
31	prescription of the substitution in the same manner as provided
32	<u>in s. 465.025(3)(a).</u>
33	(d) The pharmacist, within 5 business days after
34	dispensing the substitute biological product in lieu of the
35	prescribed biological product, notifies the prescribing health
36	care provider of the substitution by facsimile, telephone,
37	voicemail, e-mail, electronic medical record, or other
38	electronic means.
39	(e) The pharmacist and the prescribing health care
40	provider each retain a written record of the substitution for at
41	least 4 years.
42	(3) The board shall maintain on its public website a
43	current list of biological products that the United States Food
44	and Drug Administration has determined are biosimilar and
45	interchangeable as provided in paragraph (2)(a).
46	Section 2. This act shall take effect July 1, 2013.

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