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CS/CS/HB 365, Engrossed 1

2013 Legislature

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

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

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

20 465.019 Institutional pharmacies; permits.—

21 (6) In a Class II institutional pharmacy, an institutional
 22 formulary system may be adopted with approval of the medical
 23 staff for the purpose of identifying those medicinal drugs, ~~and~~
 24 proprietary preparations, biologics, biosimilars, and biosimilar
 25 interchangeables that may be dispensed by the pharmacists
 26 employed in such institution. A facility with a Class II
 27 institutional permit which is operating under the formulary
 28 system shall establish policies and procedures for the



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29 development of the system in accordance with the joint standards
 30 of the American Hospital Association and American Society of
 31 Hospital Pharmacists for the utilization of a hospital formulary
 32 system, which formulary shall be approved by the medical staff.

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

35 465.0252 Substitution of interchangeable biosimilar
 36 products.—

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

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

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

46 (b) The prescribing health care provider does not express
 47 a preference against substitution in writing, verbally, or
 48 electronically.

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

52 (d) The pharmacist retains a written or electronic record
 53 of the substitution for at least 2 years.

54 (3) A pharmacist who practices in a class II or modified
 55 class II institutional pharmacy shall comply with the
 56 notification provisions of paragraph (2) (c) by entering the



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57 substitution in the institution's written medical record system
58 or electronic medical record system.

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

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