

1 A bill to be entitled
 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

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 or the pharmacist's agent, within 5
53 business days after dispensing the substitute biological product
54 in lieu of the prescribed biological product, notifies the
55 prescribing health care provider of the substitution by
56 facsimile, telephone, voicemail, e-mail, electronic medical

57 record, or other electronic means.

58 (e) The pharmacist and the prescribing health care
59 provider each retain a written or electronic record of the
60 substitution for at least 2 years.

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

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

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