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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/25/2013	.	
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	.	

The Committee on Appropriations (Galvano) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists



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13 employed in such institution. A facility with a Class II
14 institutional permit which is operating under the formulary
15 system shall establish policies and procedures for the
16 development of the system in accordance with the joint standards
17 of the American Hospital Association and American Society of
18 Hospital Pharmacists for the utilization of a hospital formulary
19 system, which formulary shall be approved by the medical staff.

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

22 465.0252 Substitution of interchangeable biosimilar
23 products.-

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

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

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

33 (b) The prescribing health care provider does not express a
34 preference against substitution in writing, verbally, or
35 electronically.

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

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

41 (3) A pharmacist who practices in a class II or modified



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42 class II institutional pharmacy shall comply with the
43 notification provisions of paragraph (2) (c) by entering the
44 substitution in the institution's written medical record system
45 or electronic medical record system.

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

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

51
52 ===== T I T L E A M E N D M E N T =====

53 And the title is amended as follows:

54 Delete everything before the enacting clause
55 and insert:

56 A bill to be entitled
57 An act relating to pharmacy; amending s. 465.019,
58 F.S.; permitting a class II institutional pharmacy
59 formulary to include biologics, biosimilars, and
60 biosimilar interchangeables; creating s. 465.0252,
61 F.S.; providing definitions; providing requirements
62 for a pharmacist to dispense a substitute biological
63 product that is determined to be biosimilar to and
64 interchangeable for the prescribed biological product;
65 providing notification requirements for a pharmacist
66 in a class II or modified class II institutional
67 pharmacy; requiring the Board of Pharmacy to maintain
68 a current list of interchangeable biosimilar products;
69 providing an effective date.