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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/06/2009	.	
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The Committee on Health Regulation (Bennett) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Subsection (7) of section 465.003, Florida
Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(7) "Institutional formulary system" means a method whereby
the medical staff evaluates, appraises, and selects those
medicinal drugs or proprietary preparations which in the medical
staff's clinical judgment are most useful in patient care, and



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12 which are available for dispensing by a practicing pharmacist
13 for in a Class I or in a Class II institutional pharmacy.

14 Section 2. Subsection (6) of section 465.019, Florida
15 Statutes, is amended, and subsection (7) is added to that
16 section, to read:

17 465.019 Institutional pharmacies; permits.-

18 (6) In a Class I or Class II institutional pharmacy, an
19 institutional formulary system may be adopted with approval of
20 the medical staff for the purpose of identifying those medicinal
21 drugs and proprietary preparations that may be dispensed by a
22 practicing pharmacist for a Class I or in a Class II
23 institutional pharmacy ~~the pharmacists employed in such~~
24 ~~institution.~~ A facility that has with a Class I or Class II
25 institutional permit which is operating under the formulary
26 system shall establish policies and procedures for the
27 development of the system, in accordance with the joint
28 standards of the American Hospital Association and American
29 Society of Hospital Pharmacists, for the use ~~utilization~~ of an
30 institutional a hospital formulary system, which ~~formulary~~ shall
31 be approved by the medical staff.

32 (7) The policies and procedures for an institutional
33 formulary system in a Class I institutional pharmacy shall:

34 (a) Be approved by the medical staff.

35 (b) Openly provide detailed methods and criteria for the
36 selection and objective evaluation of all available
37 pharmaceuticals.

38 (c) Include policies for the development, maintenance,
39 approval, dissemination, and notification to prescribers of the
40 drug formulary and for continuous and comprehensive review of



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41 formulary drugs.

42 (d) Provide for regular monitoring of compliance with the
43 policies and procedures and of clinical outcomes in
44 circumstances in which a substitution of drugs has occurred.

45 (e) Provide a mechanism to inform the prescriber prior to
46 any substitution of drugs by using a method of communication
47 designated by the prescriber for such purpose. The method of
48 communication designated by the prescriber shall be noted in the
49 patient's chart.

50 (f) Establish a process that allows any individual
51 prescriber to opt out of the formulary system entirely.

52 (g) Establish a process that allows any individual
53 prescriber to opt out of the formulary system with respect to a
54 particular patient.

55 (h) Provide a mechanism to ensure that patients or
56 guardians are informed of any change of an existing prescription
57 to a formulary substitute.

58 (i) Include policies stating that practitioners are not
59 penalized for prescribing nonformulary drug products that are
60 medically necessary.

61 (j) Be consistent with applicable state and federal laws
62 and with rules of the department and board.

63 Section 3. Paragraph (b) of subsection (1) of section
64 627.4239, Florida Statutes, is amended to read:

65 627.4239 Coverage for use of drugs in treatment of cancer.—

66 (1) DEFINITIONS.—As used in this section, the term:

67 (b) "Standard reference compendium" means an authoritative
68 compendium identified by the Secretary of the United States
69 Department of Health and Human Services and recognized by the



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70 federal Centers for Medicare and Medicaid Services;

71 ~~1. The United States Pharmacopeia Drug Information;~~

72 ~~2. The American Medical Association Drug Evaluations; or~~

73 ~~3. The American Hospital Formulary Service Drug~~

74 ~~Information.~~

75 Section 4. This act shall take effect July 1, 2009.

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77 ===== T I T L E A M E N D M E N T =====

78 And the title is amended as follows:

79 Delete everything before the enacting clause

80 and insert:

81 A bill to be entitled

82 An act relating to prescribed drugs; amending ss.

83 465.003 and 465.019, F.S.; authorizing the use of an

84 institutional formulary system in a Class I

85 institutional pharmacy at which, with certain

86 exceptions, all medicinal drugs are administered from

87 individual prescription containers to the patient and

88 medicinal drugs are not dispensed on the premises;

89 specifying requirements for the policies and

90 procedures of such an institutional formulary system;

91 amending s. 627.4239, F.S.; revising the definition of

92 the term "standard reference compendium" for purposes

93 of regulating the insurance coverage of drugs used in

94 the treatment of cancer; providing an effective date.