**By** the Committee on Health Regulation; and Senator Peaden

588-04443-09 20091868c1

A bill to be entitled

An act relating to prescribed drugs; amending ss. 465.003 and 465.019, F.S.; authorizing the use of an institutional formulary system in a Class I institutional pharmacy at which, with certain exceptions, all medicinal drugs are administered from individual prescription containers to the patient and medicinal drugs are not dispensed on the premises; specifying requirements for the policies and procedures of such an institutional formulary system; amending s. 627.4239, F.S.; revising the definition of the term "standard reference compendium" for purposes of regulating the insurance coverage of drugs used in the treatment of cancer; providing an effective date.

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

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 which are available for dispensing by a practicing pharmacist <u>for</u> ~~in~~ a <u>Class I or in a</u> Class II institutional pharmacy.

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

465.019 Institutional pharmacies; permits.—

(6) In a Class I or 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 that may be dispensed by a practicing pharmacist for a Class I or in a Class II institutional pharmacy ~~the pharmacists employed in such institution~~. A facility that has ~~with~~ a Class I or Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system, in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists, for the use ~~utilization~~ of an institutional ~~a hospital~~ formulary system, which ~~formulary~~ shall be approved by the medical staff.

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

(a) Be approved by the medical staff.

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

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

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

(e) Provide a mechanism to inform the prescriber prior to

any substitution of drugs by using a method of communication designated by the prescriber for such purpose. The method of communication designated by the prescriber shall be noted in the patient's chart.

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

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

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

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

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

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

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

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

(b) "Standard reference compendium" means an authoritative compendium identified by the Secretary of the United States Department of Health and Human Services and recognized by the federal Centers for Medicare and Medicaid Services~~:~~

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

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

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

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