By Senator Bean

4-00744A-19 2019706__

A bill to be entitled

An act relating to institutional pharmacies; amending s. 465.003, F.S.; revising the definition of the term "institutional formulary system"; amending s. 465.019, F.S.; authorizing the use of an institutional formulary system in a Class I institutional pharmacy; specifying requirements for the policies and procedures of an institutional formulary system in a Class I institutional pharmacy; 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 that, ~~which~~ in the clinical judgment of the medical staff, ~~staff's clinical judgment~~ are most useful in patient care~~,~~ and ~~which~~ are available for dispensing by a practicing pharmacist for a Class I institutional pharmacy, or a practicing pharmacist in a Class II institutional pharmacy or a Class III institutional pharmacy, as those terms are defined in s. 465.019(2).

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

465.019 Institutional pharmacies; permits.—

(2) The following classes of institutional pharmacies are established:

(a) "Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(6) In a Class I institutional pharmacy, a Class II institutional pharmacy, or a Class III institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by a practicing pharmacist for a Class I institutional pharmacy, or dispensed by a practicing pharmacist in a Class II institutional pharmacy or a Class III institutional pharmacy, who is employed by the institutional pharmacy ~~the pharmacists employed in such institution~~. A facility that has ~~with~~ a Class I institutional pharmacy permit, a Class II institutional pharmacy permit, or a Class III institutional pharmacy 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 must ~~formulary shall~~ be approved by the medical staff.

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

(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 must be noted in the patient's chart.

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

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

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

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

Section 3. This act shall take effect July 1, 2019.