By the Committees on Health and Human Services Appropriations; and Health Regulation; and Senator Peaden

603-05155-09 20091868c2

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; amending s. 456.42, F.S.; revising provisions specifying the information required to be included in written prescriptions for medicinal drugs; amending s. 893.04, F.S.; authorizing a pharmacist to dispense a controlled substance and require photographic identification without documenting certain information; authorizing a pharmacist to dispense a controlled substance without verification of certain information by the prescriber under certain circumstances; 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 for ~~in~~ a Class I or in a 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 on the prescription for such purpose. The method of communication designated by the prescriber shall be noted in the patient's chart. The prescriber must provide annual written prior approval for the substitution of drugs on the institutional formulary to be allowed for the prescriber's patients.

(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. Section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.—A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed ~~in both textual and numerical formats~~, and the directions for use of the drug; must be dated ~~with the month written out in textual letters~~; and must be signed by the prescribing practitioner on the day when issued. A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats and must be dated with the abbreviated month written out on the face of

the prescription. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

Section 5. Paragraph (d) of subsection (2) of section 893.04, Florida Statutes, is amended to read:

893.04 Pharmacist and practitioner.—

(2)

(d) Each written prescription prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity of the controlled substance prescribed on the face of the prescription and a notation of the date, with the abbreviated month written out on the face of the prescription. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed

another prescription for the person to whom the prescription was written.

Section 6. This act shall take effect July 1, 2009.