By Senator Stargel

22-00467E-18 20181128__

A bill to be entitled

An act relating to pharmacy; amending s. 465.003, F.S.; defining and redefining terms; amending s. 465.004, F.S.; revising the membership of the Board of Pharmacy; amending s. 465.019, F.S.; establishing Class III institutional pharmacies; authorizing such pharmacies to dispense, compound, and fill prescriptions, prepare prepackaged drug products, and conduct other pharmaceutical services between certain entities under common control; defining the term "common control"; providing that the lawful dispensing and distribution of medicinal drugs by Class III institutional pharmacies is not considered wholesale distribution; requiring such pharmacies to maintain certain policies and procedures; conforming provisions to changes made by the act; amending s. 465.0252, F.S.; conforming a provision to changes made by the act; amending s. 499.003, F.S.; revising the definition of the term "prepackaged drug product"; amending s. 499.01, F.S.; providing that a prescription drug repackager permit and a restricted prescription drug distributor permit are not required for the distribution of medicinal drugs or prepackaged drug products between entities under common control under certain circumstances; providing that a certain hospital is not required to hold a restricted prescription drug distributor permit under certain circumstances; deleting a provision exempting certain drug repackagers from specified permit requirements;

providing an effective date.

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

Section 1. Subsections (7) and (13) of section 465.003, Florida Statutes, are amended, and subsection (21) is added to that section, 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 medical staff's clinical judgment are most useful in patient care, and that ~~which~~ are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy.

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such

provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189 and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

(21) "Central distribution facility" means a facility under common control with a hospital holding a Class III institutional pharmacy permit which may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.

Section 2. Subsection (2) of section 465.004, Florida Statutes, is amended to read:

465.004 Board of Pharmacy.—

(2) Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at

least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, two must be currently engaged in the practice of pharmacy in a community pharmacy, two must be currently engaged in the practice of pharmacy in a Class II, ~~institutional pharmacy or a~~ modified Class II, or Class III institutional pharmacy, and three must be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older. The Governor shall appoint members to the board in accordance with this subsection as members' terms expire or as a vacancy occurs until the composition of the board complies with the requirements of this subsection.

Section 3. Subsections (4) and (6) of section 465.019, Florida Statutes, are amended, and paragraph (d) is added to subsection (2) of that section, to read:

465.019 Institutional pharmacies; permits.—

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

(d)1. "Class III institutional pharmacies" are those institutional pharmacies, including central distribution facilities, which are affiliated with a hospital and provide the same services as those authorized for Class II institutional pharmacies in subsection (6). Class III institutional pharmacies may dispense, distribute, compound, and fill prescriptions for

medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services for the affiliated hospital and entities under common control, each of which must be permitted under this chapter to possess medicinal drugs. A Class III institutional pharmacy may provide such medicinal drugs, drug products, and pharmaceutical services to an entity under common control that holds an active health care clinic establishment permit as described in s. 499.01(2)(r). For purposes of this chapter, the term "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or other means. The dispensing or distribution of a medicinal drug by a Class III institutional pharmacy pursuant to this section is not considered wholesale distribution as defined in s. 499.003.

2. A Class III institutional pharmacy shall maintain policies and procedures that identify or otherwise address:

a. The consultant pharmacist responsible for pharmaceutical services.

b. Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.

c. Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products.

d. Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.

e. Medicinal drugs and prepackaged drug products that may

not be safely distributed among Class III institutional pharmacies.

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II or Class III institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(6) In a Class II or 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 the pharmacists employed in such institution. A facility with a Class II or 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 utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

Section 4. Subsection (3) of section 465.0252, Florida Statutes, is amended to read:

465.0252 Substitution of interchangeable biosimilar products.—

(3) A pharmacist who practices in a Class II, ~~or~~ modified Class II, or Class III institutional pharmacy shall comply with the notification provisions of paragraph (2)(c) by entering the substitution in the institution's written medical record system or electronic medical record system.

Section 5. Subsection (39) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(39) "Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 ~~for the purpose of dispensing in the establishment in which the prepackaging occurred~~.

Section 6. Paragraphs (b) and (h) of subsection (2) and subsection (5) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.—

(2) The following permits are established:

(b) *Prescription drug repackager permit.*—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer.

2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

3. A prescription drug repackager permit is not required for the distribution of medicinal drugs or prepackaged drug products between entities under common control if each entity holds an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" means the same as in s. 465.019(2).

(h) *Restricted prescription drug distributor permit.*—

1. A restricted prescription drug distributor permit is required for:

a. Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(48)(a).

b. Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or

the manufacturer of the drug.

c. A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(48)(j) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II) Blood-collection containers approved under s. 505 of the federal act;

(III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent

any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2. Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121.

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

5. A restricted prescription drug distributor permit is not required for distributions between pharmacies that each hold an active permit under chapter 465, have a common ownership, and are operating in a freestanding end-stage renal dialysis clinic, if such distributions are made to meet the immediate emergency medical needs of specifically identified patients and do not occur with such frequency as to amount to the regular and systematic supplying of that drug between the pharmacies. The department shall adopt rules establishing when the distribution of a prescription drug under this subparagraph amounts to the regular and systematic supplying of that drug.

6. A restricted prescription drug distributor permit is not required for the distribution of medicinal drugs or prepackaged drug products between entities under common control if each entity holds an active Class III institutional pharmacy permit under chapter 465 or an active health care clinic establishment permit under paragraph (r). For purposes of this subparagraph, the term "common control" means the same as in s. 465.019(2).

7. A restricted prescription drug distributor permit is not required for a hospital covered by s. 340B of the Public Health Service Act, 42 U.S.C. s. 256b, if such hospital arranges for a prescription drug wholesale distributor to distribute prescription drugs covered under that act directly to a contract pharmacy.

~~(5) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in~~

~~the state for their own use, pursuant to s. 499.003(48)(a)3., if:~~

~~(a) The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;~~

~~(b) The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;~~

~~(c) The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and~~

~~(d) The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.~~

~~The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection. A prescription drug distributor that repackages and distributes prescription drugs under this subsection to a not-for-profit rural hospital, as defined in s. 395.602, is not required to comply with paragraph (c) or paragraph (d), but must provide to each health care entity for which it repackages, for~~

~~each prescription drug that is repackaged and distributed, the information required by department rule for labeling prescription drugs. The department shall adopt rules to ensure the safety and integrity of prescription drugs repackaged and distributed under this subsection, including rules regarding prescription drug manufacturing and labeling requirements.~~

Section 7. This act shall take effect July 1, 2018.