By Senator Grimsley

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A bill to be entitled

An act relating to remote dispensing site pharmacies; amending s. 465.003, F.S.; redefining the term "pharmacy" to include remote dispensing site pharmacies; providing that an offsite pharmacist who supervises a registered pharmacy technician at a remote dispensing site is not considered to be not present or off duty; amending s. 465.014, F.S.; authorizing registered pharmacy technicians to compound and dispense medicinal drugs when operating under the electronic supervision of an offsite pharmacist; amending s. 465.015, F.S.; conforming provisions to changes made by the act; creating s. 465.0198, F.S.; providing permit requirements for remote dispensing site pharmacies; providing a permitting process for such pharmacies; providing requirements for such pharmacies; providing that such pharmacies are not considered pharmacy locations for certain purposes; authorizing such pharmacies to store, hold, and dispense medicinal drugs; prohibiting such pharmacies from performing centralized prescription filling; requiring such pharmacies to maintain a policy and procedures manual that includes specified information; amending s. 465.022, F.S.; authorizing a registered pharmacist to serve as the prescription department manager at up to a specified number of remote dispensing site pharmacies under certain conditions; amending s. 465.0265, F.S.; conforming a provision to changes made by the act;

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providing an effective date.

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

Section 1. Subsection (11) of section 465.003, Florida Statutes, is amended to read:

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

- (11) (a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy, and a remote dispensing site pharmacy.
- 1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- 2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
- 3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
- 4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
  - 5. The term "Internet pharmacy" includes locations not

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otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

- 6. The term "remote dispensing site pharmacy" includes every location where medicinal drugs are compounded or dispensed by a registered pharmacy technician who is electronically supervised by an offsite pharmacist and which is overseen by a prescription department manager.
- (b) The pharmacy department of any permittee <u>is shall be</u> considered closed whenever a <del>Florida licensed</del> pharmacist is not present and on duty. The term "not present and on duty" <u>may</u> shall not be construed to prevent:
- $\underline{\text{1.}}$  A pharmacist from exiting the prescription department for the purposes of:
- $\underline{a}$ . Consulting or responding to inquiries or providing assistance to patients or customers;
  - b. Attending to personal hygiene needs;  $\tau$  or
- $\underline{\text{c.}}$  Performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.
- 2. An offsite pharmacist from electronically supervising a registered pharmacy technician at a remote dispensing site pharmacy.

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Section 2. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.

- (1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, however:
- (a) except that A licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision.
- (b) A registered pharmacy technician who is registered pursuant to this section may compound and dispense medicinal drugs when operating under the electronic supervision of an offsite pharmacist pursuant to s. 465.0198.

A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

Section 3. Subsections (1) and (2) of section 465.015,

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Florida Statutes, are amended to read:

465.015 Violations and penalties.-

- (1) It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:
- (a) Which is not registered under the provisions of this chapter.
- (b) In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs. This paragraph does not apply to any person who owns, operates, maintains, opens, establishes, conducts, or has charge of a remote dispensing site pharmacy pursuant to s. 465.0198.
  - (2) It is unlawful for any person:
- (a) To make a false or fraudulent statement, either for herself or himself or for another person, in any application, affidavit, or statement presented to the board or in any proceeding before the board.
- (b) To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist. This paragraph does not apply to a registered pharmacy technician preparing or dispensing medicinal drugs pursuant to s. 465.0198.
  - (c) To sell or dispense drugs as defined in s. 465.003(8)

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without first being furnished with a prescription.

(d) To sell samples or complimentary packages of drug products.

Section 4. Section 465.0198, Florida Statutes, is created to read:

465.0198 Remote dispensing site pharmacy permits.-

- (1) Any person desiring a permit to operate a remote dispensing site pharmacy shall apply to the department for a remote dispensing site pharmacy permit. If the board certifies that the application complies with the laws and rules of the board governing the practice of the profession of pharmacy, the department must issue the permit. A permit may not be issued unless a pharmacist is designated as the prescription department manager responsible for the oversight of the remote dispensing site pharmacy.
  - (2) A remote dispensing site pharmacy must:
- (a) Be jointly owned by a supervising pharmacy or operated under a contract with a supervising pharmacy. For purposes of this subsection, "supervising pharmacy" means a pharmacy licensed under this chapter which employs a pharmacist who remotely supervises a registered pharmacy technician at a remote dispensing site pharmacy.
- (b) Display a sign visible to the public indicating that the location is a remote dispensing site pharmacy and that the facility is under 24-hour video surveillance. The remote dispensing site pharmacy must retain the video surveillance recordings for at least 45 days after the date they are recorded.
  - (c) Be located at least 10 miles from an existing community

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pharmacy, unless:

- 1. The applicant for the proposed remote dispensing site pharmacy demonstrates to the board that the proposed remote dispensing site pharmacy will promote public health without unduly harming an existing community pharmacy located within the 10-mile radius;
- 2. The community pharmacy that is located within the 10-mile radius from the remote dispensing site pharmacy is an institutional pharmacy; or
- 3. A community pharmacy opens within 10 miles of an existing remote dispensing site pharmacy.
- (d) Ensure that the prescription department manager visits the remote dispensing site pharmacy on a schedule determined by the board to inspect the pharmacy and address personnel matters.
- (e) Provide clinical services for patients and must notify the department within 10 days after any change in the employment of the prescription department manager.
- (3) A remote dispensing site pharmacy is not considered a pharmacy location for purposes of network access in managed care programs.
- (4) A remote dispensing site pharmacy may store, hold, and dispense all medicinal drugs including those listed in s. 893.03.
- (5) A remote dispensing site pharmacy may not perform centralized prescription filling, as defined in s. 465.003(16).
- (6) A remote dispensing site pharmacy must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual must include:

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(a) A description of how the remote dispensing site pharmacy will comply with federal and state laws, rules, and regulations.

- (b) The procedure for supervising the remote dispensing site pharmacy and counseling its patients.
- (c) The procedure for reviewing the prescription drug inventory and drug records maintained by the remote dispensing site pharmacy.
- (d) The policy and procedure for providing appropriate security to protect the confidentiality and integrity of patient information.
- (e) The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote dispensing site pharmacy's operation.
- (f) The procedure by which the prescription department manager uses the state prescription drug monitoring program before authorizing any controlled substance for dispensing.
- (g) The procedure for maintaining a perpetual inventory of the controlled substances listed in s. 893.03(2).
- (h) The specific duties, tasks, and functions that a registered pharmacy technician is authorized to perform at the remote dispensing site pharmacy.
- Section 5. Paragraph (c) of subsection (11) of section 465.022, Florida Statutes, is amended to read:
  - 465.022 Pharmacies; general requirements; fees.-
- (11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

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(c) A registered pharmacist may not serve as the prescription department manager in more than one location unless approved by the board. However, a registered pharmacist may serve as a prescription department manager for up to two remote dispensing site pharmacies that are under common control.

Section 6. Subsection (1) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.-

(1) A pharmacy licensed under this chapter, other than a remote dispensing site pharmacy permitted under s. 465.0198, may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

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