## LEGISLATIVE ACTION Senate House Comm: RCS 02/06/2018

The Committee on Health Policy (Grimsley) recommended the following:

## Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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.

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- 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 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 prepared by a

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registered pharmacy technician who is electronically supervised by an offsite pharmacist and dispensed pursuant to s. 465.014(1) to the patient after verification, certification, and counseling by the pharmacist.

- (b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" may shall not be construed to prevent:
- 1. A pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers; 7
  - 2. A pharmacist attending to personal hygiene needs; , or
- 3. A pharmacist 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; or
- 4. An offsite pharmacist from remotely supervising a registered pharmacy technician at a remote dispensing site pharmacy.

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, 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). However, a registered pharmacy technician may dispense medicinal drugs when operating under the

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electronic supervision of an offsite Florida licensed pharmacist pursuant to s. 465.0198. 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. 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, 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.

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(2) It is unlawful for any person:

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(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 dispensing medicinal drugs pursuant to s. 465.0198.
- (c) To sell or dispense drugs as defined in s. 465.003(8) 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 must apply to the department for a remote dispensing site pharmacy permit. If the board certifies that the application complies with the laws and board rules governing the practice of the profession of pharmacy, the department must issue the permit. A permit may not be issued unless a licensed pharmacist or consultant pharmacist is designated as the prescription department manager responsible

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for the oversight of the remote dispensing site pharmacy. The permittee must notify the department within 10 days after any change of the prescription department manager.

- (2) As a prerequisite to issuance of an initial permit or a permit for a change of location, the remote dispensing site pharmacy must pass an onsite inspection. The department must make the inspection within 90 days before issuance of the permit.
  - (3) The 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 licensed pharmacy in this state which employs a Florida licensed 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.
- (c) Be located in an area defined as rural pursuant to s. 381.0406 and be at least 10 miles from an existing community pharmacy, unless the remote dispensing site pharmacy is located in a hospital licensed under chapter 395 or in a clinic. For purposes of this paragraph, the term "clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, excluding a mobile clinic and a portable equipment provider.
  - (4) A remote dispensing site pharmacy may not lose its

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permit based on the subsequent opening of a community pharmacy within 10 miles of the remote dispensing site pharmacy.

- (5) A remote dispensing site pharmacy may store, hold, and dispense all medicinal drugs including those listed in s. 893.03(3)-(5). A remote dispensing pharmacy may not store, hold, or dispense narcotic controlled substances listed in s. 893.03(2).
- (6) A remote dispensing site pharmacy may not perform centralized prescription filling, as defined in s. 465.003(16).
- (7) 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 shall include:
- (a) A description of how the 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 before the dispensing of any medicinal drug pursuant to this section.
- (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 pharmacist from supervising the remote dispensing site pharmacy's operation.
- (f) The procedure by which a supervising pharmacist consults the state prescription drug monitoring program before

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authorizing any controlled substance for dispensing and reports the dispensing of a controlled substance as required under s. 893.055.

- (q) The specific duties, tasks, and functions that a registered pharmacy technician is authorized to perform at the remote dispensing site pharmacy.
- (8) The prescription department manager or other pharmacist employed by the supervising pharmacy must visit the remote dispensing site pharmacy, based on a schedule designated by the board, to inspect the pharmacy, address personnel matters, and provide clinical services for patients.
- (9) A registered pharmacy technician must have completed at least 2,080 hours of experience at a pharmacy within the 2 years immediately preceding the date on which the registered pharmacy technician begins employment at the remote dispensing site pharmacy.
- (10) A registered pharmacy technician working at a remote dispensing site pharmacy may not perform sterile or complex nonsterile compounding.
- (11) This section does not alter the supervision requirements established in s. 465.014.

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:
  - (c) A Florida licensed registered pharmacist may not serve



as the prescription department manager in more than one location unless approved by the board. However, a Florida licensed pharmacist may serve as a prescription department manager for no more than two remote dispensing site pharmacies, if such pharmacies are under common control.

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

465.0265 Centralized prescription filling.-

(1) Except as otherwise provided in this chapter, a pharmacy licensed under this chapter 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.

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======= T I T L E A M E N D M E N T ========= And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to telepharmacy; amending s. 465.003, F.S.; revising and providing definitions; amending s. 465.014, F.S.; authorizing a registered pharmacy technician to dispense medicinal drugs under certain conditions; amending s. 465.015, F.S.; conforming provisions to changes made by the act; creating s.

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465.0198, F.S.; providing permit requirements for remote dispensing site pharmacies; providing operating requirements and prohibitions for a remote dispensing site pharmacy; defining the term "clinic"; requiring the prescription department manager or other pharmacist employed by the supervising pharmacy to visit the remote dispensing site pharmacy; providing an experience requirement for a registered pharmacy technician working at a remote site pharmacy; prohibiting a registered pharmacy technician from performing sterile or nonsterile compounding; providing construction; amending s. 465.022, F.S.; authorizing a Florida licensed pharmacist to serve as the prescription drug manager at more than one remote dispensing site pharmacy under certain conditions; amending s. 465.0265, F.S.; conforming provisions to changes made by the act; providing an effective date.