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A bill to be entitled An act relating to pharmacy; amending s. 465.003, F.S.; revising the definition of the term "pharmacy" to include remote-site pharmacies; revising construction of the term "not present and on duty"; amending s. 465.014, F.S.; authorizing registered pharmacy technicians to handle the sales transactions and delivery of dispensed drugs under certain circumstances; providing an exception to certain supervision limitations; amending s. 465.015, F.S.; providing applicability; exempting certain registered pharmacy technicians from specified prohibitions; creating s. 465.0198, F.S.; defining terms; providing for the permitting of remote-site pharmacies; requiring that a licensed or consultant pharmacist serve as the prescription department manager of a remote-site pharmacy; requiring remote-site pharmacies to notify the Department of Health of a change in the pharmacy's prescription department manager within a specified timeframe; providing requirements for remote-site pharmacies; authorizing remote-site pharmacies to store, hold, and dispense medicinal drugs; prohibiting the dispensing of Schedule II medications at remote-site pharmacies unless a pharmacist is present; requiring prescription

Page 1 of 10

department managers to visit remote-site pharmacies, based on a certain schedule, to perform specified tasks; prohibiting remote-site pharmacies from being open when the supervising pharmacy is closed unless a certain pharmacist is present or providing remote supervision at the remote-site pharmacy; authorizing the Board of Pharmacy to adopt specified rules; amending s. 465.022, F.S.; exempting registered pharmacists serving as prescription department managers for remote-site pharmacies from certain practice limitations; providing an effective date.

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

Section 1. Subsection (20) of section 465.003, Florida Statutes, is amended to read:

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

- (20)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy, and a remote-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

Page 2 of 10

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 the profession of pharmacy.
- 6. The term "remote-site pharmacy" includes every location where medicinal drugs are dispensed by a supervising pharmacist as defined in s. 465.0198 who is remotely supervising a

Page 3 of 10

registered pharmacy technician handling the sales transactions and delivery of the drugs.

- (b) The pharmacy department of any permittee <u>is</u> shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" <u>may</u> shall not be construed to prevent any of the following:
- $\underline{1.}$ A pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers.
 - 2. A pharmacist from, attending to personal hygiene needs.
- 3. A pharmacist from, or 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.
- 4. A supervising pharmacist as defined in s. 465.0198, acting in the capacity of a prescription department manager, from remotely supervising a registered pharmacy technician at a remote-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

Page 4 of 10

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those duties, tasks, and functions that do not fall within the purview of s. 465.003, and a registered pharmacy technician operating under remote supervision of a supervising pharmacist as defined in s. 465.0198 may handle the sales transactions and delivery of the dispensed drugs. 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, except as provided in s. 465.0198 or 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. Paragraph (b) of subsection (1) and paragraph (b) of subsection (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:

Page 5 of 10

| (b) In which a person not licensed as a pharmacist in this |
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| 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. $\underline{\text{This}}$ |
| paragraph does not apply to any person who owns, operates, |
| maintains, opens, establishes, conducts, or has charge of a |
| remote-site pharmacy under s. 465.0198. |

(2) It is unlawful for any person:

(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, ex is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist, or is not a registered pharmacy technician at a remote-site pharmacy who is acting under remote supervision of a licensed pharmacist pursuant to s. 465.0198.

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

- 465.0198 Remote-site pharmacy permits.-
- (1) As used in this section, the term:
- (a) "Supervising pharmacist" means a pharmacist licensed in this state who is employed by or under contract with a pharmacy licensed in this state and who remotely supervises registered pharmacy technicians at a remote-site pharmacy at a

Page 6 of 10

maximum ratio of one pharmacist to up to six registered pharmacy
technicians.

- (b) "Supervising pharmacy" means a pharmacy licensed in this state which employs or contracts with a pharmacist licensed in this state who remotely supervises a registered pharmacy technician at a remote-site pharmacy at a ratio of one pharmacist to up to six registered pharmacy technicians.
- c) "Telepharmacy" means the practice of pharmacy by a pharmacist located in this state using telecommunications or other automations and technologies to provide or supervise the provision of pharmacy services to patients and their agents who are located at sites other than where the pharmacist is located, including dispensing of prescriptions to and counseling of patients.
- (2) Any person desiring a permit to operate a remote-site pharmacy must apply to the department. If the board certifies that the application complies with the laws and rules of the board, 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 for the oversight of the remote-site pharmacy. The permittee must notify the department within 10 days after any change of the prescription department manager.
- (3) A remote-site pharmacy must comply with all of the following:

| | | (a) | Ве | jointly | owned | by | or | operated | under | а | contract | with |
|---|-----|------|------|-----------|-------|----|----|----------|-------|---|----------|------|
| а | sup | ervi | sing | g pharmad | cy. | | | | | | | |

(b) Be open between the hours of 7 p.m. to 9 a.m., in accordance with subsection (6).

- (c) Maintain a video surveillance system that records continuously 24 hours a day, 7 days a week, and retain video surveillance recordings for at least 30 days.
- (d) Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is under 24-hour video surveillance.
- (e) Maintain a policies and procedures manual, which must be made available to the board or its agent upon request and must include, but need not be limited to, all of the following:
- 1. A description of how the remote-site pharmacy will comply with federal and state laws and rules.
- 2. The procedures for supervising the remote-site pharmacy and counseling its patients.
- 3. The procedures for reviewing the prescription drug inventory and drug records maintained by the remote-site pharmacy.
- 4. The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.
- 5. The written plan for recovery from an event that interrupts or prevents the prescription department manager from

Page 8 of 10

201 <u>supervising the remote-site pharmacy's operation.</u>

- 6. The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance.
- 7. The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03.
- 8. The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote-site pharmacy.
- (4) A remote-site pharmacy may store, hold, or dispense any medicinal drug, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.
- (5) The prescription department manager must visit the remote-site pharmacy, based on a schedule determined by the board, to inspect the pharmacy, address personnel matters, and provide clinical services for patients.
- (6) A remote-site pharmacy may only be open when the supervising pharmacy is open, unless a pharmacist employed by or under contract with the supervising pharmacy, or a pharmacy under contract with the supervising pharmacy, is present at the remote-site pharmacy or is providing remote supervision as required under this section.

| 226 | (7) The board may adopt rules as necessary to specify |
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| 227 | additional criteria for a remote-site pharmacy. Any additional |
| 228 | criteria adopted by the board must be limited to rules |
| 229 | concerning one or more of the following: |
| 230 | (a) Application requirements. |
| 231 | (b) Structural and equipment requirements. |
| 232 | (c) Training requirements. |
| 233 | (d) Inventory recordkeeping and storage requirements. |
| 234 | Section 5. Paragraph (c) of subsection (11) of section |
| 235 | 465.022, Florida Statutes, is amended to read: |
| 236 | 465.022 Pharmacies; general requirements; fees |
| 237 | (11) A permittee must notify the department of the |
| 238 | identity of the prescription department manager within 10 days |
| 239 | after employment. The prescription department manager must |
| 240 | comply with the following requirements: |
| 241 | (c) A registered pharmacist may not serve as the |
| 242 | prescription department manager in more than one location $_{\underline{\prime}}$ |
| 243 | except when acting as a prescription department manager under s. |
| 244 | 465.0198, unless approved by the board. |
| 245 | Section 6. This act shall take effect July 1, 2025. |
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Page 10 of 10