| 1  |   |
|----|---|
| 2  | A bill to be entitled                                     |
| 3  | An act relating to telepharmacy; amending s. 465.003,     |
| 4  | F.S.; revising and providing definitions; amending s.     |
| 5  | 465.014, F.S.; authorizing a registered pharmacy          |
| 6  | technician to dispense medicinal drugs under certain      |
| 7  | conditions; amending s. 465.015, F.S.; conforming         |
| 8  | provisions to changes made by the act; creating s.        |
| 9  | 465.0198, F.S.; providing permit requirements for         |
| 10 | remote dispensing site pharmacies; providing              |
| 11 | requirements and prohibitions for a remote dispensing     |
| 12 | site pharmacy; requiring the prescription department      |
| 13 | manager to visit the remote dispensing site pharmacy;     |
| 14 | providing an experience requirement for a registered      |
| 15 | pharmacy technician working at a remote site pharmacy;    |
| 16 | prohibiting a registered pharmacy technician from         |
| 17 | performing sterile or nonsterile compounding;             |
| 18 | providing construction; amending s. 465.022, F.S.;        |
| 19 | authorizing a Florida licensed pharmacist to serve as     |
| 20 | the prescription drug manager at more than one remote     |
| 21 | dispensing site pharmacy under certain conditions;        |
| 22 | amending s. 465.0265, F.S.; conforming provisions to      |
| 23 | changes made by the act; providing an effective date.     |
| 24 |   |
| 25 | Be It Enacted by the Legislature of the State of Florida: |
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26 27 Section 1. Subsection (11) of section 465.003, Florida 28 Statutes, is amended to read: 29 465.003 Definitions.-As used in this chapter, the term: 30 (11) (a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, 31 and an Internet pharmacy, and a remote dispensing site pharmacy. 32 33 The term "community pharmacy" includes every location 1. where medicinal drugs are compounded, dispensed, stored, or sold 34 35 or where prescriptions are filled or dispensed on an outpatient 36 basis. The term "institutional pharmacy" includes every 37 2. location in a hospital, clinic, nursing home, dispensary, 38 39 sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where 40 medicinal drugs are compounded, dispensed, stored, or sold. 41 42 3. The term "nuclear pharmacy" includes every location 43 where radioactive drugs and chemicals within the classification 44 of medicinal drugs are compounded, dispensed, stored, or sold. 45 The term "nuclear pharmacy" does not include hospitals licensed 46 under chapter 395 or the nuclear medicine facilities of such hospitals. 47 The term "special pharmacy" includes every location 48 4. where medicinal drugs are compounded, dispensed, stored, or sold 49 50 if such locations are not otherwise defined in this subsection. Page 2 of 10

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The term "Internet pharmacy" includes locations not 51 5. otherwise licensed or issued a permit under this chapter, within 52 53 or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use 54 55 such communication or information to fill or refill 56 prescriptions or to dispense, distribute, or otherwise engage in 57 the practice of pharmacy in this state. Any act described in 58 this definition constitutes the practice of pharmacy as defined in subsection (13). 59

6. The term "remote dispensing site pharmacy" includes
 61 every location where medicinal drugs are dispensed by a
 62 registered pharmacy technician who is electronically supervised
 63 by an off-site prescription department manager.

(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" shall
not be construed to prevent:

68 <u>1.</u> A pharmacist from exiting the prescription department 69 for the purposes of consulting or responding to inquiries or 70 providing assistance to patients or customers; $_{7}$ 

71

2. A pharmacist attending to personal hygiene needs; - or

72 <u>3. A pharmacist performing any other function for which</u> 73 the pharmacist is responsible, provided that such activities are 74 conducted in a manner consistent with the pharmacist's 75 responsibility to provide pharmacy services<u>; or</u>

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76 4. An off-site pharmacist from remotely supervising a 77 registered pharmacy technician at a remote dispensing site 78 pharmacy. 79 Section 2. Subsection (1) of section 465.014, Florida 80 Statutes, is amended to read: 81 465.014 Pharmacy technician.-82 (1) A person other than a licensed pharmacist or pharmacy 83 intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to 84 85 pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the 86 87 purview of s. 465.003(13). However, a registered pharmacy technician may dispense medicinal drugs when operating under the 88 89 electronic supervision of an off-site Florida licensed 90 pharmacist pursuant to s. 465.0198. All such delegated acts must be performed under the direct supervision of a licensed 91 92 pharmacist who is responsible for all such acts performed by 93 persons under his or her supervision. A registered pharmacy 94 technician, under the supervision of a pharmacist, may initiate 95 or receive communications with a practitioner or his or her 96 agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one 97 registered pharmacy technician unless otherwise permitted by the 98 guidelines adopted by the board. The board shall establish 99 100 guidelines to be followed by licensees or permittees in

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101 determining the circumstances under which a licensed pharmacist 102 may supervise more than one pharmacy technician. 103 Section 3. Subsections (1) and (2) of section 465.015, 104 Florida Statutes, are amended to read: 105 465.015 Violations and penalties.-106 It is unlawful for any person to own, operate, (1)107 maintain, open, establish, conduct, or have charge of, either 108 alone or with another person or persons, a pharmacy: 109 Which is not registered under the provisions of this (a) 110 chapter. In which a person not licensed as a pharmacist in this 111 (b) 112 state or not registered as an intern in this state or in which 113 an intern who is not acting under the direct and immediate 114 personal supervision of a licensed pharmacist fills, compounds, 115 or dispenses any prescription or dispenses medicinal drugs. This 116 paragraph does not apply to any person who owns, operates, 117 maintains, opens, establishes, conducts, or has charge of a 118 remote dispensing site pharmacy pursuant to s. 465.0198. 119 (2) It is unlawful for any person: 120 To make a false or fraudulent statement, either for (a) 121 herself or himself or for another person, in any application, 122 affidavit, or statement presented to the board or in any

(b) To fill, compound, or dispense prescriptions or todispense medicinal drugs if such person does not hold an active

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proceeding before the board.

123

| 126 | license as a pharmacist in this state, is not registered as an  |
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| 127 | intern in this state, or is an intern not acting under the      |
| 128 | direct and immediate personal supervision of a licensed         |
| 129 | pharmacist. This paragraph does not apply to a registered       |
| 130 | pharmacy technician dispensing medicinal drugs pursuant to s.   |
| 131 | 465.0198.   |
| 132 | (c) To sell or dispense drugs as defined in s. 465.003(8)       |
| 133 | without first being furnished with a prescription.              |
| 134 | (d) To sell samples or complimentary packages of drug           |
| 135 | products.   |
| 136 | Section 4. Section 465.0198, Florida Statutes, is created       |
| 137 | to read:  |
| 138 | 465.0198 Remote dispensing site pharmacy permits                |
| 139 | (1) Any person desiring a permit to operate a remote            |
| 140 | dispensing site pharmacy shall apply to the department for a    |
| 141 | remote dispensing site pharmacy permit. If the board certifies  |
| 142 | that the application complies with the laws and rules of the    |
| 143 | board governing the practice of the profession of pharmacy, the |
| 144 | department shall issue the permit. A permit may not be issued   |
| 145 | unless a licensed pharmacist or consultant pharmacist is        |
| 146 | designated as the prescription department manager responsible   |
| 147 | for the oversight of the remote dispensing site pharmacy. The   |
| 148 | permittee must notify the department within 10 days after any   |
| 149 | change of the prescription department manager.                  |
| 150 |   |
|     | (2) As a prerequisite to issuance of an initial permit or       |

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| 151 | a permit for a change of location, the remote site pharmacy must |
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| 152 | pass an onsite inspection. The department must make the          |
| 153 | inspection within 90 days before issuance of the permit.         |
| 154 | (3) The remote dispensing site pharmacy must:                    |
| 155 | (a) Be jointly owned by a supervising pharmacy or operated       |
| 156 | under a contract with a supervising pharmacy. For purposes of    |
| 157 | this subsection, "supervising pharmacy" means a licensed         |
| 158 | pharmacy in this state that employs a Florida licensed           |
| 159 | pharmacist who remotely supervises a registered pharmacy         |
| 160 | technician at a remote dispensing site pharmacy.                 |
| 161 | (b) Display a sign visible to the public indicating that         |
| 162 | the location is a remote dispensing site pharmacy and that the   |
| 163 | facility is under 24-hour video surveillance. The remote         |
| 164 | dispensing site pharmacy must retain the video surveillance      |
| 165 | recordings for at least 45 days.                                 |
| 166 | (c) Be located in an area defined as rural pursuant to s.        |
| 167 | 381.0406.  |
| 168 | (d) Be at least 10 miles from an existing community              |
| 169 | pharmacy.  |
| 170 | (4) A remote dispensing site pharmacy may not lose its           |
| 171 | permit based on the subsequent opening of a community pharmacy   |
| 172 | within 10 miles of the remote dispensing site pharmacy.          |
| 173 | (5) A remote dispensing site pharmacy is not considered a        |
| 174 | pharmacy location for purposes of network access in managed care |
| 175 | programs.  |
|     |  |

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| 176 | (6) A remote dispensing site pharmacy may store, hold, and       |
|-----|--|
| 177 | dispense all medicinal drugs including those listed in s.        |
| 178 | 893.03(3)-(5). A remote dispensing pharmacy may not store, hold, |
| 179 | or dispense controlled substances listed in s. 893.03(2).        |
| 180 | (7) A remote dispensing site pharmacy may not perform            |
| 181 | centralized prescription filling, as defined in s. 465.003(16).  |
| 182 | (8) A remote dispensing site pharmacy must maintain a            |
| 183 | policy and procedures manual, which shall be made available to   |
| 184 | the board or its agent upon request. The policy and procedures   |
| 185 | manual shall include:  |
| 186 | (a) A description of how the pharmacy will comply with           |
| 187 | federal and state laws, rules, and regulations.                  |
| 188 | (b) The procedure for supervising the remote dispensing          |
| 189 | site pharmacy and counseling its patients prior to the           |
| 190 | dispensing of any medicinal drug pursuant to this section.       |
| 191 | (c) The procedure for reviewing the prescription drug            |
| 192 | inventory and drug records maintained by the remote dispensing   |
| 193 | site pharmacy.   |
| 194 | (d) The policy and procedure for providing appropriate           |
| 195 | security to protect the confidentiality and integrity of patient |
| 196 | information.   |
| 197 | (e) The written plan for recovery from an event that             |
| 198 | interrupts or prevents the pharmacist from supervising the       |
| 199 | remote dispensing site pharmacy's operation.                     |
| 200 | (f) The procedure by which a supervising pharmacist              |
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201 consults the state prescription drug monitoring program before 202 authorizing any controlled substance for dispensing and submits 203 the dispensing of a controlled substance as required under s. 204 893.055. 205 (q) The specific duties, tasks, and functions that a registered pharmacy technician is authorized to perform at the 206 207 remote dispensing site pharmacy. 208 The prescription department manager must visit the (9) 209 remote dispensing site pharmacy, based on a schedule designated 210 by the board, to inspect the pharmacy, address personnel 211 matters, and provide clinical services for patients. 212 (10) A registered pharmacy technician must have completed 213 at least 2,080 hours of experience at a pharmacy within the 2 214 years immediately preceding the date on which the registered 215 pharmacy technician begins employment at the remote dispensing 216 site pharmacy. 217 (11) A registered pharmacy technician working at a remote 218 dispensing site pharmacy may not perform sterile or nonsterile 219 compounding. 220 (12) This section does not alter the supervision requirements established in s. 465.014. 221 222 Section 5. Paragraph (c) of subsection (11) of section 465.022, Florida Statutes, is amended to read: 223 224 465.022 Pharmacies; general requirements; fees.-225 (11) A permittee must notify the department of the

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identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(c) A <u>Florida licensed</u> registered pharmacist may not serve
as the prescription department manager in more than one location
unless approved by the board. <u>However, a Florida licensed</u>
<u>pharmacist may serve as a prescription department manager in</u>
<u>more than one, but no more than two, remote dispensing site</u>
<u>pharmacies, if such pharmacies are under common control.</u>

235 Section 6. Subsection (1) of section 465.0265, Florida 236 Statutes, is amended to read:

237

465.0265 Centralized prescription filling.-

238 Except as otherwise provided in this chapter, a (1)239 pharmacy licensed under this chapter may perform centralized 240 prescription filling for another pharmacy, provided that the 241 pharmacies have the same owner or have a written contract 242 specifying the services to be provided by each pharmacy, the 243 responsibilities of each pharmacy, and the manner in which the 244 pharmacies will comply with federal and state laws, rules, and 245 regulations.

246

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

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