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

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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 registered pharmacy technician who is electronically supervised by an off-site pharmacist and dispensed pursuant to s.

66 465.014(1) to the patient after the pharmacist:

a. Verifies the dosage and directions.

b. Certifies the accuracy of the final preparation.c. Engages in patient counseling.

(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:

74 <u>1.</u> A pharmacist from exiting the prescription department
 75 for the purposes of consulting or responding to inquiries or

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76 providing assistance to patients or customers;  $\tau$ 77 2. A pharmacist attending to personal hygiene needs; - or 78 3. A pharmacist performing any other function for which 79 the pharmacist is responsible, provided that such activities are 80 conducted in a manner consistent with the pharmacist's 81 responsibility to provide pharmacy services; or 82 4. An off-site pharmacist from remotely supervising a 83 registered pharmacy technician at a remote dispensing site 84 pharmacy. Section 2. Subsection (1) of section 465.014, Florida 85 86 Statutes, is amended to read: 87 465.014 Pharmacy technician.-A person other than a licensed pharmacist or pharmacy 88 (1)89 intern may not engage in the practice of the profession of 90 pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section 91 92 those duties, tasks, and functions that do not fall within the 93 purview of s. 465.003(13). However, a registered pharmacy 94 technician may dispense medicinal drugs when operating under the 95 electronic supervision of an off-site Florida licensed 96 pharmacist pursuant to s. 465.0198. All such delegated acts must 97 be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by 98 persons under his or her supervision. A registered pharmacy 99 100 technician, under the supervision of a pharmacist, may initiate

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101 or receive communications with a practitioner or his or her 102 agent, on behalf of a patient, regarding refill authorization 103 requests. A licensed pharmacist may not supervise more than one 104 registered pharmacy technician unless otherwise permitted by the 105 quidelines adopted by the board. The board shall establish 106 guidelines to be followed by licensees or permittees in 107 determining the circumstances under which a licensed pharmacist 108 may supervise more than one pharmacy technician.

Section 3. Subsections (1) and (2) of section 465.015, Florida Statutes, are amended to read:

111

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 thischapter.

117 (b) In which a person not licensed as a pharmacist in this 118 state or not registered as an intern in this state or in which 119 an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, 120 121 or dispenses any prescription or dispenses medicinal drugs. This 122 paragraph does not apply to any person who owns, operates, maintains, opens, establishes, conducts, or has charge of a 123 124 remote dispensing site pharmacy pursuant to s. 465.0198. (2) 125 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.

130 (b) To fill, compound, or dispense prescriptions or to 131 dispense medicinal drugs if such person does not hold an active 132 license as a pharmacist in this state, is not registered as an 133 intern in this state, or is an intern not acting under the 134 direct and immediate personal supervision of a licensed 135 pharmacist. This paragraph does not apply to a registered pharmacy technician dispensing medicinal drugs pursuant to s. 136 137 465.0198.

138 (c) To sell or dispense drugs as defined in s. 465.003(8)139 without first being furnished with a prescription.

140 (d) To sell samples or complimentary packages of drug141 products.

142 Section 4. Section 465.0198, Florida Statutes, is created 143 to read:

144465.0198 Remote dispensing site pharmacy permits.-145(1) Any person desiring a permit to operate a remote146dispensing site pharmacy shall apply to the department for a147remote dispensing site pharmacy permit. If the board certifies148that the application complies with the laws and rules of the149board governing the practice of the profession of pharmacy, the150department shall issue the permit. A permit may not be issued

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151	unless a licensed pharmacist or consultant pharmacist is
152	designated as the prescription department manager responsible
153	for the oversight of the remote dispensing site pharmacy. The
154	permittee must notify the department within 10 days after any
155	change of the prescription department manager.
156	(2) As a prerequisite to issuance of an initial permit or
157	a permit for a change of location, the remote dispensing site
158	pharmacy must pass an onsite inspection. The department must
159	make the inspection within 90 days before issuance of the
160	permit.
161	(3) The remote dispensing site pharmacy must:
162	(a) Be jointly owned by a supervising pharmacy or operated
163	under a contract with a supervising pharmacy. For purposes of
164	this subsection, "supervising pharmacy" means a licensed
165	pharmacy in this state that employs a Florida licensed
166	pharmacist who remotely supervises a registered pharmacy
167	technician at a remote dispensing site pharmacy.
168	(b) Display a sign visible to the public indicating that
169	the location is a remote dispensing site pharmacy and that the
170	facility is under 24-hour video surveillance. The remote
171	dispensing site pharmacy must retain the video surveillance
172	recordings for at least 45 days.
173	(c) Be located in an area defined as rural pursuant to s.
174	381.0406.
175	(d) Be at least 10 miles from an existing community
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176 pharmacy. 177 (4) A remote dispensing site pharmacy may not lose its 178 permit based on the subsequent opening of a community pharmacy 179 within 10 miles of the remote dispensing site pharmacy. 180 (5) A remote dispensing site pharmacy is not considered a 181 pharmacy location for purposes of network access in managed care 182 programs. (6) A remote dispensing site pharmacy may store, hold, and 183 dispense all medicinal drugs, including those listed in s. 184 185 893.03(3)-(5). A remote dispensing pharmacy may not store, hold, 186 or dispense controlled substances listed in s. 893.03(2). 187 (7) A remote dispensing site pharmacy may not perform 188 centralized prescription filling, as defined in s. 465.003(16). 189 (8) A remote dispensing site pharmacy must maintain a 190 policy and procedures manual, which shall be made available to 191 the board or its agent upon request. The policy and procedures 192 manual shall include: 193 (a) A description of how the pharmacy will comply with 194 federal and state laws, rules, and regulations. 195 The procedure for supervising the remote dispensing (b) 196 site pharmacy and counseling its patients prior to the 197 dispensing of any medicinal drug pursuant to this section. (C) 198 The procedure for reviewing the prescription drug 199 inventory and drug records maintained by the remote dispensing 200 site pharmacy.

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201	(d) The policy and procedure for providing appropriate
202	security to protect the confidentiality and integrity of patient
203	information.
204	(e) The written plan for recovery from an event that
205	interrupts or prevents the pharmacist from supervising the
206	operation of the remote dispensing site pharmacy.
207	(f) The procedure by which a supervising pharmacist
208	consults the state prescription drug monitoring program before
209	authorizing any controlled substance for dispensing and submits
210	the dispensing of a controlled substance as required under s.
211	893.055.
212	(g) The specific duties, tasks, and functions that a
213	registered pharmacy technician is authorized to perform at the
214	remote dispensing site pharmacy.
215	(9) The prescription department manager or other Florida-
216	licensed pharmacist must visit the remote dispensing site
217	pharmacy, based on a schedule designated by the board, to
218	inspect the pharmacy, address personnel matters, and provide
219	clinical services for patients.
220	(10) A registered pharmacy technician must have completed
221	at least 2,080 hours of experience at a pharmacy within the 2
222	years immediately preceding the date on which the registered
223	pharmacy technician begins employment at the remote dispensing
224	site pharmacy.
225	(11) A registered pharmacy technician working at a remote
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226	dispensing site pharmacy may not perform sterile or nonsterile
227	compounding, except that a registered pharmacy technician may
228	reconstitute orally administered powder antibiotics.
229	(12) This section does not alter the supervision
230	requirements established in s. 465.014.
231	Section 5. Paragraph (c) of subsection (11) of section
232	465.022, Florida Statutes, is amended to read:
233	465.022 Pharmacies; general requirements; fees
234	(11) A permittee must notify the department of the
235	identity of the prescription department manager within 10 days
236	after employment. The prescription department manager must
237	comply with the following requirements:
238	(c) A <u>Florida licensed</u> <del>registered</del> pharmacist may not serve
239	as the prescription department manager in more than one location
240	unless approved by the board. However, a Florida licensed
241	pharmacist may serve as a prescription department manager in
242	more than one, but no more than two, remote dispensing site
243	pharmacies, if such pharmacies are under common control.
244	Section 6. Subsection (1) of section 465.0265, Florida
245	Statutes, is amended to read:
246	465.0265 Centralized prescription filling
247	(1) Except as otherwise provided in this chapter, a
248	pharmacy licensed under this chapter may perform centralized
249	prescription filling for another pharmacy, provided that the
250	pharmacies have the same owner or have a written contract
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251 specifying the services to be provided by each pharmacy, the 252 responsibilities of each pharmacy, and the manner in which the 253 pharmacies will comply with federal and state laws, rules, and 254 regulations.

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

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