1 A bill to be entitled 2 An act relating to pharmacy; amending s. 465.003, 3 F.S.; revising the definition of the term "dispense"; 4 revising the definition of the term "pharmacy" to 5 include remote-site pharmacies; revising construction 6 of the term "not present and on duty"; amending s. 7 465.014, F.S.; authorizing registered pharmacy 8 technicians to dispense medicinal drugs under certain 9 circumstances; providing an exception to certain supervision limitations; amending s. 465.015, F.S.; 10 11 providing applicability; exempting certain registered pharmacy technicians from specified prohibitions; 12 13 creating s. 465.0198, F.S.; defining the terms "supervising pharmacy" and "telepharmacy"; providing 14 for the permitting of remote-site pharmacies; 15 16 requiring a licensed or consultant pharmacist to serve 17 as the prescription department manager of a remote-18 site pharmacy; requiring remote-site pharmacies to 19 notify the Department of Health of a change in the pharmacy's prescription department manager within a 20 21 specified timeframe; providing requirements for remote-site pharmacies; authorizing remote-site 22 23 pharmacies to store, hold, and dispense medicinal 24 drugs; prohibiting the dispensing of Schedule II 25 medications at remote-site pharmacies unless a

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26	pharmacist is present; requiring prescription
27	department managers to visit remote-site pharmacies,
28	based on a certain schedule, to perform specified
29	tasks; prohibiting remote-site pharmacies from being
30	open when the supervising pharmacy is closed unless a
31	certain pharmacist is present or providing remote
32	supervision at the remote-site pharmacy; prohibiting
33	registered pharmacists from serving as prescription
34	department managers for more than three remote-site
35	pharmacies under certain circumstances; authorizing
36	the Board of Pharmacy to adopt specified rules;
37	amending s. 465.022, F.S.; exempting registered
38	pharmacists serving as prescription department
39	managers for remote-site pharmacies from certain
40	practice limitations; providing an effective date.
41	
42	Be It Enacted by the Legislature of the State of Florida:
43	
44	Section 1. Subsections (13) and (20) of section 465.003,
45	Florida Statutes, are amended to read:
46	465.003 DefinitionsAs used in this chapter, the term:
47	(13) "Dispense" means the transfer of possession of one or
48	more doses of a medicinal drug by a pharmacist, or by a
49	registered pharmacy technician who is remotely supervised by an
50	offsite pharmacist, to the ultimate consumer or her or his
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51 agent. As an element of dispensing, the pharmacist shall, prior 52 to the actual physical transfer, interpret and assess the 53 prescription order for potential adverse reactions, 54 interactions, and dosage regimen she or he deems appropriate in 55 the exercise of her or his professional judgment, and the 56 pharmacist shall certify that the medicinal drug called for by 57 the prescription is ready for transfer. The pharmacist shall 58 also provide counseling on proper drug usage, either orally or 59 in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction 60 61 and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing. 62

(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.

70 2. The term "institutional pharmacy" includes every 71 location in a hospital, clinic, nursing home, dispensary, 72 sanitarium, extended care facility, or other facility, 73 hereinafter referred to as "health care institutions," where 74 medicinal drugs are compounded, dispensed, stored, or sold. 75 3. The term "nuclear pharmacy" includes every location

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76 where radioactive drugs and chemicals within the classification 77 of medicinal drugs are compounded, dispensed, stored, or sold. 78 The term "nuclear pharmacy" does not include hospitals licensed 79 under chapter 395 or the nuclear medicine facilities of such 80 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.

84 5. The term "Internet pharmacy" includes locations not 85 otherwise licensed or issued a permit under this chapter, within 86 or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use 87 such communication or information to fill or refill 88 89 prescriptions or to dispense, distribute, or otherwise engage in 90 the practice of pharmacy in this state. Any act described in 91 this definition constitutes the practice of the profession of 92 pharmacy.

93 <u>6. The term "remote-site pharmacy" includes every location</u> 94 where medicinal drugs are dispensed by a registered pharmacy 95 <u>technician who is remotely supervised by an offsite pharmacist</u> 96 acting in the capacity of a prescription department manager.

97 (b) The pharmacy department of any permittee <u>is shall be</u> 98 considered closed whenever a Florida licensed pharmacist is not 99 present and on duty. The term "not present and on duty" <u>may</u> 100 shall not be construed to prevent <u>any of the following:</u>

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101 <u>1.</u> A pharmacist from exiting the prescription department 102 for the purposes of consulting or responding to inquiries or 103 providing assistance to patients or customers.

104

2. A pharmacist from, attending to personal hygiene needs.

105 <u>3. A pharmacist from, or performing any other function for</u> 106 which the pharmacist is responsible, provided that such 107 activities are conducted in a manner consistent with the 108 pharmacist's responsibility to provide pharmacy services.

109 <u>4. An offsite pharmacist, acting in the capacity of a</u>
 110 prescription department manager, from remotely supervising a
 111 registered pharmacy technician at a remote-site pharmacy.

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

114

465.014 Pharmacy technician.-

115 A person other than a licensed pharmacist or pharmacy (1)116 intern may not engage in the practice of the profession of 117 pharmacy, except that a licensed pharmacist may delegate to 118 pharmacy technicians who are registered pursuant to this section 119 those duties, tasks, and functions that do not fall within the purview of s. 465.003, and a registered pharmacy technician 120 operating under remote supervision of an offsite pharmacist 121 under s. 465.0198 may dispense medicinal drugs under such 122 123 supervision. All such delegated acts must be performed under the 124 direct supervision of a licensed pharmacist who is responsible 125 for all such acts performed by persons under his or her

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126 supervision. A registered pharmacy technician, under the 127 supervision of a pharmacist, may initiate or receive 128 communications with a practitioner or his or her agent, on 129 behalf of a patient, regarding refill authorization requests. A 130 licensed pharmacist may not supervise more than one registered pharmacy technician, except as provided in s. 465.0198 or unless 131 132 otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or 133 134 permittees in determining the circumstances under which a 135 licensed pharmacist may supervise more than one pharmacy 136 technician.

Section 3. Paragraph (b) of subsection (1) and paragraph (b) of subsection (2) of section 465.015, Florida Statutes, are amended to read:

140

465.015 Violations and penalties.-

141 (1) It is unlawful for any person to own, operate,
142 maintain, open, establish, conduct, or have charge of, either
143 alone or with another person or persons, a pharmacy:

(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

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151	remote-site pharmacy under s. 465.0198.
152	(2) It is unlawful for any person:
153	(b) To fill, compound, or dispense prescriptions or to
154	dispense medicinal drugs if such person does not hold an active
155	license as a pharmacist in this state, is not registered as an
156	intern in this state, $rac{\partial \mathbf{r}}{\partial \mathbf{r}}$ is an intern not acting under the
157	direct and immediate personal supervision of a licensed
158	pharmacist, or is not a registered pharmacy technician at a
159	remote-site pharmacy who is acting under remote supervision of a
160	licensed pharmacist pursuant to s. 465.0198.
161	Section 4. Section 465.0198, Florida Statutes, is created
162	to read:
163	465.0198 Remote-site pharmacy permits
164	(1) As used in this section, the term:
164 165	(1) As used in this section, the term: (a) "Supervising pharmacy" means a pharmacy licensed in
165	(a) "Supervising pharmacy" means a pharmacy licensed in
165 166	(a) "Supervising pharmacy" means a pharmacy licensed in this state which employs or contracts with a pharmacist licensed
165 166 167	(a) "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
165 166 167 168	(a) "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
165 166 167 168 169	(a) "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.
165 166 167 168 169 170	(a) "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. (b) "Telepharmacy" means the practice of pharmacy by a
165 166 167 168 169 170 171	(a) "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. (b) "Telepharmacy" means the practice of pharmacy by a pharmacist located in this state using telecommunications or
165 166 167 168 169 170 171 172	(a) "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. (b) "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
165 167 168 169 170 171 172 173	(a) "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. (b) "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

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176	patients.
177	(2) Any person desiring a permit to operate a remote-site
178	pharmacy must apply to the department. If the board certifies
179	that the application complies with the laws and rules of the
180	board, the department must issue the permit. A permit may not be
181	issued unless a licensed pharmacist or consultant pharmacist is
182	designated as the prescription department manager responsible
183	for the oversight of the remote-site pharmacy. The permittee
184	must notify the department within 10 days after any change of
185	the prescription department manager.
186	(3) A remote-site pharmacy must comply with all of the
187	following:
188	(a) Be jointly owned by or operated under a contract with
189	a supervising pharmacy.
190	(b) Maintain a video surveillance system that records
191	continuously 24 hours per day and retain video surveillance
192	recordings for at least 30 days.
193	(c) Display a sign visible to the public indicating that
194	the location is a remote-site pharmacy and that the facility is
195	under 24-hour video surveillance.
196	(d) Maintain a policies and procedures manual, which must
197	be made available to the board or its agent upon request and
198	must include, but need not be limited to, all of the following:
199	1. A description of how the pharmacy will comply with
200	federal and state laws and rules.

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201	2. The procedures for supervising the remote-site pharmacy
202	and counseling its patients.
203	3. The procedures for reviewing the prescription drug
204	inventory and drug records maintained by the remote-site
205	pharmacy.
206	4. The policies and procedures for providing security
207	adequate to protect the confidentiality and integrity of patient
208	information.
209	5. The written plan for recovery from an event that
210	interrupts or prevents the prescription department manager from
211	supervising the remote-site pharmacy's operation.
212	6. The procedures for use of the state prescription drug
213	monitoring program by the prescription department manager before
214	he or she may authorize the dispensing of any controlled
215	substance.
216	7. The procedures for maintaining a perpetual inventory of
217	the controlled substances listed in Schedule II of s. 893.03.
218	8. The specific duties, tasks, and functions that
219	registered pharmacy technicians are authorized to perform at the
220	remote-site pharmacy.
221	(4) A remote-site pharmacy may store, hold, or dispense
222	any medicinal drug, including proprietary drugs and controlled
223	substances. However, a remote-site pharmacy may not dispense
224	Schedule II controlled substances listed in s. 893.03 unless a
225	pharmacist is present at the remote-site pharmacy.
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226	(5) The prescription department manager must visit the
227	remote-site pharmacy, based on a schedule determined by the
228	board, to inspect the pharmacy, address personnel matters, and
229	provide clinical services for patients.
230	(6) A remote-site pharmacy may not be open when the
231	supervising pharmacy is closed, unless a pharmacist employed by
232	or under contract with the supervising pharmacy, or a pharmacy
233	under contract with the supervising pharmacy, is present at the
234	remote-site pharmacy or is providing remote supervision as
235	required under this section.
236	(7) A registered pharmacist may not serve as the
237	prescription department manager for more than three remote-site
238	pharmacies that are under common control of the same supervising
239	pharmacy, at a ratio of one pharmacist to up to six registered
240	pharmacy technicians at each remote-site pharmacy.
241	(8) The board may adopt rules as necessary to specify
242	additional criteria for a remote-site pharmacy. Any additional
243	criteria adopted by the board must be limited to rules
244	concerning one or more of the following:
245	(a) Application requirements.
246	(b) Structural and equipment requirements.
247	(c) Training requirements.
248	(d) Inventory recordkeeping and storage requirements.
249	Section 5. Paragraph (c) of subsection (11) of section
250	465.022, Florida Statutes, is amended to read:

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FLORIDA HOUSE (OF REPRESENTATIVES
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251 465.022 Pharmacies; general requirements; fees.-252 (11) A permittee must notify the department of the 253 identity of the prescription department manager within 10 days 254 after employment. The prescription department manager must 255 comply with the following requirements: 256 (c) A registered pharmacist may not serve as the 257 prescription department manager in more than one location, except as authorized under s. 465.0198, unless approved by the 258 259 board. 260 Section 6. This act shall take effect July 1, 2024.

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