Bill No. HB 493 (2024)

Amendment No.

COMMITTEE/SUBCOMMITTEE	ACTION
ADOPTED	(Y/N)
ADOPTED AS AMENDED	(Y/N)
ADOPTED W/O OBJECTION	(Y/N)
FAILED TO ADOPT	(Y/N)
WITHDRAWN	(Y/N)
OTHER	

Committee/Subcommittee hearing bill: Healthcare Regulation 1 2 Subcommittee 3 Representative Roach offered the following: 4 5 Amendment (with title amendment) 6 Remove everything after the enacting clause and insert: 7 Section 1. Subsection (20) of section 465.003, Florida 8 Statutes, is amended to read: 465.003 Definitions.-As used in this chapter, the term: 9 (20) (a) "Pharmacy" includes a community pharmacy, an 10 institutional pharmacy, a nuclear pharmacy, a special pharmacy, 11 and an Internet pharmacy, and a remote-site pharmacy. 12 1. The term "community pharmacy" includes every location 13 where medicinal drugs are compounded, dispensed, stored, or sold 14 15 or where prescriptions are filled or dispensed on an outpatient 16 basis. 654971 - h0493-strike all.docx Published On: 1/31/2024 7:35:24 PM

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17 2. The term "institutional pharmacy" includes every 18 location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, 19 20 hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold. 21 22 3. The term "nuclear pharmacy" includes every location 23 where radioactive drugs and chemicals within the classification 24 of medicinal drugs are compounded, dispensed, stored, or sold. 25 The term "nuclear pharmacy" does not include hospitals licensed 26 under chapter 395 or the nuclear medicine facilities of such 27 hospitals. 4. The term "special pharmacy" includes every location 28 29 where medicinal drugs are compounded, dispensed, stored, or sold 30 if such locations are not otherwise defined in this subsection. 5. The term "Internet pharmacy" includes locations not 31 otherwise licensed or issued a permit under this chapter, within 32 or outside this state, which use the Internet to communicate 33 with or obtain information from consumers in this state and use 34 35 such communication or information to fill or refill 36 prescriptions or to dispense, distribute, or otherwise engage in 37 the practice of pharmacy in this state. Any act described in 38 this definition constitutes the practice of the profession of 39 pharmacy. 40 6. The term "remote-site pharmacy" means a location where medicinal drugs are dispensed by a supervising pharmacist as 41

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defined in s. 465.0198 who is acting in the capacity of a

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43 prescription department manager and remotely supervising a registered pharmacy technician handling the sales transactions 44 45 and delivery of the drugs. (b) The pharmacy department of any permittee is shall be 46 47 considered closed whenever a Florida licensed pharmacist is not 48 present and on duty. The term "not present and on duty" may 49 shall not be construed to prevent any of the following: 50 1. A pharmacist from exiting the prescription department 51 for the purposes of consulting or responding to inquiries or providing assistance to patients or customers. 52 53 2. A pharmacist from τ attending to personal hygiene needs. 3. A pharmacist from $- \sigma r$ performing any other function for 54 55 which the pharmacist is responsible, provided that such 56 activities are conducted in a manner consistent with the 57 pharmacist's responsibility to provide pharmacy services. 4. A supervising pharmacist as defined in s. 465.0198, 58 acting in the capacity of a prescription department manager, 59 60 from remotely supervising a registered pharmacy technician at a remote-site pharmacy. 61 62 Section 2. Subsection (1) of section 465.014, Florida 63 Statutes, is amended to read, and Subsection (10) of section 465.014, Florida Statutes, is created to read: 64 65 465.014 Pharmacy technician.-(1) A person other than a licensed pharmacist or pharmacy 66 67 intern may not engage in the practice of the profession of pharmacy as defined in s. 465.003, except that a licensed 68 654971 - h0493-strike all.docx Published On: 1/31/2024 7:35:24 PM Page 3 of 9

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69 pharmacist may delegate to pharmacy technicians who are 70 registered pursuant to this section those duties, tasks, and 71 functions that do not fall within the purview of s. 465.003. Except as otherwise provided in this section, aAll such 72 delegated acts must be performed under the direct supervision of 73 74 a licensed pharmacist who is responsible for all such acts 75 performed by persons under his or her supervision. A registered 76 pharmacy technician, under the supervision of a pharmacist, may 77 initiate or receive communications with a practitioner or his or 78 her agent, on behalf of a patient, regarding refill 79 authorization requests. A licensed pharmacist may not supervise 80 more than one registered pharmacy technician or unless otherwise permitted by the guidelines adopted by the board. The board 81 82 shall establish guidelines to be followed by licensees or 83 permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy 84 85 technician. 86 (10) A pharmacy technician may perform the delegated acts 87 authorized by this section at a remote-site pharmacy under the remote <u>supervision of a licensed supervising pharmacist as</u> 88 89 defined in s. 465.0198. A licensed supervising pharmacist may 90 not remotely supervise more than six registered pharmacy 91 technicians. 92 Section 3. Section 465.0198, Florida Statutes, is created to read: 93 465.0198 Remote-site pharmacy permits.-94 654971 - h0493-strike all.docx Published On: 1/31/2024 7:35:24 PM

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95	(1) As used in this section, the term:
96	(a) "Supervising pharmacist" means a pharmacist licensed in
97	this state employed by or under contract with a pharmacy
98	licensed in this state who remotely supervises registered
99	pharmacy technicians at a remote-site pharmacy.
100	(b) "Supervising pharmacy" means a pharmacy licensed in
101	this state which employs or contracts with a pharmacist licensed
102	in this state to serve as the supervising pharmacist for a
103	remote-site pharmacy that is jointly owned by or operated under
104	a contract with the pharmacy.
105	(2) Any person desiring a permit to operate a remote-site
106	pharmacy must apply to the department. If the board certifies
107	that the application complies with the laws and rules of the
108	board, the department must issue the permit. A permit may not be
109	issued unless a licensed pharmacist or consultant pharmacist is
110	designated as the prescription department manager responsible
111	for the oversight of the remote-site pharmacy. The permittee
112	must notify the department within 10 days after any change of
113	the prescription department manager.
114	(3) A remote-site pharmacy must comply with all of the
115	following:
116	(a) Be jointly owned by or operated under a contract with a
117	supervising pharmacy.
118	(b) Maintain a video surveillance system that records
119	continuously 24 hours per day and retain video surveillance
120	recordings for at least 30 days.
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121	(c) Display a sign visible to the public indicating that
122	the location is a remote-site pharmacy and that the facility is
123	under 24-hour video surveillance.
124	(d) Maintain a policies and procedures manual, which must
125	be made available to the board or its agent upon request and
126	must include, but need not be limited to, all of the following:
127	1. A description of how the pharmacy will comply with
128	federal and state laws and rules.
129	2. The procedures for supervising the remote-site pharmacy
130	and counseling its patients.
131	3. The procedures for reviewing the prescription drug
132	inventory and drug records maintained by the remote-site
133	pharmacy.
134	4. The policies and procedures for providing security
135	adequate to protect the confidentiality and integrity of patient
136	information.
137	5. The written plan for recovery from an event that
138	interrupts or prevents the prescription department manager from
139	supervising the remote-site pharmacy's operation.
140	6. The procedures for use of the state prescription drug
141	monitoring program by the prescription department manager before
142	he or she may authorize the dispensing of any controlled
143	substance.
144	7. The procedures for maintaining a perpetual inventory of
145	the controlled substances listed in Schedule II of s. 893.03.
146	8. The specific duties, tasks, and functions that
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	\mathbf{D} which are $1/21/2024$ 7 , $2\mathbf{E}$, 24 \mathbf{D}

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147	registered pharmacy technicians are authorized to perform at the	
148	remote-site pharmacy.	
149	(4) A remote-site pharmacy may store, hold, or dispense any	
150	medicinal drug, including proprietary drugs and controlled	
151	substances. However, a remote-site pharmacy may not dispense	
152	Schedule II controlled substances listed in s. 893.03 unless a	
153	pharmacist is present at the remote-site pharmacy.	
154	(5) The prescription department manager must visit the	
155	remote-site pharmacy, based on a schedule determined by the	
156	board, to inspect the pharmacy, address personnel matters, and	
157	provide clinical services for patients.	
158	(6) A remote-site pharmacy may not be open when the	
159	supervising pharmacy is closed, unless a supervising pharmacist	
160	is present at the remote-site pharmacy or is providing remote	
161	supervision as required under this section.	
162	(7) The board may adopt rules necessary to specify	
163	additional criteria for a remote-site pharmacy related to:	
164	(a) Application requirements.	
165	(b) Structural and equipment requirements.	
166	(c) Training requirements.	
167	(d) Inventory recordkeeping and storage requirements.	
168	Section 4. Paragraph (c) of subsection (11) of section	
169	465.022, Florida Statutes, is amended to read:	
170	465.022 Pharmacies; general requirements; fees	
171	(11) A permittee must notify the department of the	
172	identity of the prescription department manager within 10 days	
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173	after employment. The prescription department manager must
174	comply with the following requirements:
175	(c) A registered pharmacist may not serve as the
176	prescription department manager in more than one location,
177	except as authorized under s. 465.0198, unless approved by the
178	board.
179 180	Section 5. This act shall take effect July 1, 2024.
181	
182	TITLE AMENDMENT
183	Remove everything before the enacting clause and insert:
184	An act relating to pharmacy; amending s. 465.003, F.S.; revising
185	the definition of the term "pharmacy" to include remote-site
186	pharmacies; revising construction of the term "not present and
187	on duty"; amending s. 465.014, F.S.; authorizing registered
188	pharmacy technicians to perform delegated tasks at a remote-site
189	pharmacy under remote supervision; establishing the maximum
190	number of registered pharmacy technicians that a pharmacist can
191	remotely supervise; creating s. 465.0198, F.S.; defining the
192	terms "supervising pharmacist" and "supervising pharmacy";
193	providing for the permitting of remote-site pharmacies;
194	requiring a licensed or consultant pharmacist to serve as the
195	prescription department manager of a remote-site pharmacy;
196	requiring remote-site pharmacies to notify the Department of
197	Health of a change in the pharmacy's prescription department
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198 manager within a specified timeframe; providing requirements for 199 remote-site pharmacies; authorizing remote-site pharmacies to 200 store, hold, and dispense medicinal drugs; prohibiting the 201 dispensing of Schedule II medications at remote-site pharmacies 202 unless a pharmacist is present; requiring prescription 203 department managers to visit remote-site pharmacies, based on a 204 certain schedule, to perform specified tasks; prohibiting 205 remote-site pharmacies from being open when the supervising 206 pharmacy is closed unless a certain pharmacist is present or 207 providing remote supervision at the remote-site pharmacy; 208 authorizing the Board of Pharmacy to adopt specified rules; 209 amending s. 465.022, F.S.; exempting registered pharmacists 210 serving as prescription department managers for remote-site 211 pharmacies from certain practice limitations; providing an 212 effective date.

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