Bill No. HB 679 (2018)

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COMMITTEE/SUBCOMMITTEE ACTION ADOPTED (Y/N) ADOPTED AS AMENDED (Y/N) ADOPTED W/O OBJECTION (Y/N) FAILED TO ADOPT (Y/N) WITHDRAWN (Y/N) OTHER Committee/Subcommittee hearing bill: Health Quality

Subcommittee

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Representative Ponder offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert: Section 1. Subsection (11) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.-As used in this chapter, the term: (11) (a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy, and a remote dispensing site pharmacy.

The term "community pharmacy" includes every location 13 1. where medicinal drugs are compounded, dispensed, stored, or sold 14 or where prescriptions are filled or dispensed on an outpatient 15 16 basis.

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17 2. The term "institutional pharmacy" includes every 18 location in a hospital, clinic, nursing home, dispensary, 19 sanitarium, extended care facility, or other facility, 20 hereinafter referred to as "health care institutions," where 21 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 31 otherwise licensed or issued a permit under this chapter, within 32 33 or outside this state, which use the Internet to communicate 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 this definition constitutes the practice of pharmacy as defined 38 in subsection (13). 39

40 41 6. The term "remote dispensing site pharmacy" includes every location where medicinal drugs are dispensed by a

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42 registered pharmacy technician who is electronically supervised 43 by an off-site prescription department manager. 44 (b) The pharmacy department of any permittee shall be 45 considered closed whenever a Florida licensed pharmacist is not 46 present and on duty. The term "not present and on duty" shall 47 not be construed to prevent: 1. A pharmacist from exiting the prescription department 48 49 for the purposes of consulting or responding to inquiries or 50 providing assistance to patients or customers; τ 2. A pharmacist attending to personal hygiene needs; , or 51 52 3. A pharmacist performing any other function for which 53 the pharmacist is responsible, provided that such activities are 54 conducted in a manner consistent with the pharmacist's 55 responsibility to provide pharmacy services; or 4. An off-site pharmacist from remotely supervising a 56 57 registered pharmacy technician at a remote dispensing site 58 pharmacy. 59 Section 2. Subsection (1) of section 465.014, Florida 60 Statutes, is amended to read: 61 465.014 Pharmacy technician.-62 A person other than a licensed pharmacist or pharmacy (1) intern may not engage in the practice of the profession of 63 pharmacy, except that a licensed pharmacist may delegate to 64 pharmacy technicians who are registered pursuant to this section 65 those duties, tasks, and functions that do not fall within the 66 422357 - h0679-strike.docx Published On: 1/12/2018 4:26:38 PM

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67 purview of s. 465.003(13). However, a registered pharmacy technician may dispense medicinal drugs when operating under the 68 69 electronic supervision of an off-site Florida licensed pharmacist pursuant to s. 465.0198. All such delegated acts must 70 71 be performed under the direct supervision of a licensed 72 pharmacist who is responsible for all such acts performed by 73 persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate 74 75 or receive communications with a practitioner or his or her 76 agent, on behalf of a patient, regarding refill authorization 77 requests. A licensed pharmacist may not supervise more than one 78 registered pharmacy technician unless otherwise permitted by the 79 guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in 80 81 determining the circumstances under which a licensed pharmacist 82 may supervise more than one pharmacy technician. Section 3. Subsections (1) and (2) of section 465.015, 83 Florida Statutes, are amended to read: 84 85 465.015 Violations and penalties.-86 It is unlawful for any person to own, operate, (1)87 maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy: 88 89 (a) Which is not registered under the provisions of this chapter. 90 422357 - h0679-strike.docx

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91 In which a person not licensed as a pharmacist in this (b) 92 state or not registered as an intern in this state or in which 93 an intern who is not acting under the direct and immediate 94 personal supervision of a licensed pharmacist fills, compounds, 95 or dispenses any prescription or dispenses medicinal drugs. This 96 paragraph does not apply to any person who owns, operates, maintains, opens, establishes, conducts, or has charge of a 97 98 remote dispensing site pharmacy pursuant to s. 465.0198. 99 It is unlawful for any person: (2) To make a false or fraudulent statement, either for 100 (a) 101 herself or himself or for another person, in any application, 102 affidavit, or statement presented to the board or in any 103 proceeding before the board. To fill, compound, or dispense prescriptions or to 104 (b) 105 dispense medicinal drugs if such person does not hold an active 106 license as a pharmacist in this state, is not registered as an 107 intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed 108 109 pharmacist. This paragraph does not apply to a registered 110 pharmacy technician dispensing medicinal drugs pursuant to s. 111 465.0198. 112 To sell or dispense drugs as defined in s. 465.003(8) (C) without first being furnished with a prescription. 113 114 To sell samples or complimentary packages of drug (d) 115 products. 422357 - h0679-strike.docx Published On: 1/12/2018 4:26:38 PM

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116 Section 4. Section 465.0198, Florida Statutes, is created 117 to read: 118 465.0198 Remote dispensing site pharmacy permits.-119 (1) Any person desiring a permit to operate a remote 120 dispensing site pharmacy shall apply to the department for a 121 remote dispensing site pharmacy permit. If the board certifies that the application complies with the laws and rules of the 122 board governing the practice of the profession of pharmacy, the 123 department shall issue the permit. A permit may not be issued 124 125 unless a licensed pharmacist or consultant pharmacist is 126 designated as the prescription department manager responsible 127 for the oversight of the remote dispensing site pharmacy. The 128 permittee must notify the department within 10 days after any 129 change of the prescription department manager. 130 (2) As a prerequisite to issuance of an initial permit or 131 a permit for a change of location, the remote site pharmacy must 132 pass an onsite inspection. The department must make the 133 inspection within 90 days before issuance of the permit. 134 (3) The remote dispensing site pharmacy must: 135 (a) Be jointly owned by a supervising pharmacy or operated 136 under a contract with a supervising pharmacy. For purposes of this subsection, "supervising pharmacy" means a licensed 137 pharmacy in this state that employs a Florida licensed 138 139 pharmacist who remotely supervises a registered pharmacy 140 technician at a remote dispensing site pharmacy; 422357 - h0679-strike.docx Published On: 1/12/2018 4:26:38 PM

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141	(b) Display a sign visible to the public indicating that
142	the location is a remote dispensing site pharmacy and that the
143	facility is under 24-hour video surveillance. The remote
144	dispensing site pharmacy must retain the video surveillance
145	recordings for at least 45 days;
146	(c) Be located in an area defined as rural pursuant to s.
147	381.0406; and at least 10 miles from an existing community
148	pharmacy.
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150	(4) A remote dispensing site pharmacy may not lose its
151	permit based on the subsequent opening of a community pharmacy
152	within 10 miles of the remote dispensing site pharmacy.
153	(5) A remote dispensing site pharmacy is not considered a
154	pharmacy location for purposes of network access in managed care
155	programs.
156	(6) A remote dispensing site pharmacy may store, hold, and
157	dispense all medicinal drugs including those listed in s.
158	893.03(3)-(5). A remote dispensing pharmacy may not store, hold,
159	or dispense controlled substances listed in s. 893.03(2).
160	(7) A remote dispensing site pharmacy may not perform
161	centralized prescription filling, as defined in s. 465.003(16).
162	(8) A remote dispensing site pharmacy must maintain a
163	policy and procedures manual, which shall be made available to
164	the board or its agent upon request. The policy and procedures
165	manual shall include:
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166	(a) A decorrintian of how the pharmacy will comply with
	(a) A description of how the pharmacy will comply with
167	federal and state laws, rules, and regulations.
168	(b) The procedure for supervising the remote dispensing
169	site pharmacy and counseling its patients prior to the
170	dispensing of any medicinal drug pursuant to this section.
171	(c) The procedure for reviewing the prescription drug
172	inventory and drug records maintained by the remote dispensing
173	site pharmacy.
174	(d) The policy and procedure for providing appropriate
175	security to protect the confidentiality and integrity of patient
176	information.
177	(e) The written plan for recovery from an event that
178	interrupts or prevents the pharmacist from supervising the
179	remote dispensing site pharmacy's operation.
180	(f) The procedure by which a supervising pharmacist
181	consults the state prescription drug monitoring program before
182	authorizing any controlled substance for dispensing and submits
183	the dispensing of a controlled substance as required under s.
184	893.055.
185	
186	(g) The specific duties, tasks, and functions that a
187	registered pharmacy technician is authorized to perform at the
188	remote dispensing site pharmacy.
189	(9) The prescription department manager must visit the
190	remote dispensing site pharmacy, based on a schedule designated
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191	by the board, to inspect the pharmacy, address personnel	
192	matters, and provide clinical services for patients.	
193	(10) A registered pharmacy technician must have completed	
194	at least 2,080 hours of experience at a pharmacy within the 2	
195	years immediately preceding the date on which the registered	
196	pharmacy technician begins employment at the remote dispensing	
197	site pharmacy.	
198	(11) A registered pharmacy technician working at a remote	
199	dispensing site pharmacy may not perform sterile or nonsterile	
200	compounding.	
201	(12) Nothing in this section shall be construed to alter	
202	the supervision requirements established in s. 465.014.	
203	Section 5. Paragraph (c) of subsection (11) of section	
204	465.022, Florida Statutes, is amended to read:	
205	465.022 Pharmacies; general requirements; fees	
206	(11) A permittee must notify the department of the	
207	identity of the prescription department manager within 10 days	
208	after employment. The prescription department manager must	
209	comply with the following requirements:	
210	(c) A registered pharmacist may not serve as the	
211	prescription department manager in more than one location unless	
212	approved by the board. However, a Florida licensed pharmacist	
213	may serve as a prescription department manager in more than one,	
214	but no more than two, remote dispensing site pharmacies, if such	
215	pharmacies are under common control.	
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216 Section 6. Subsection (1) of section 465.0265, Florida 217 Statutes, is amended to read:

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465.0265 Centralized prescription filling.-

219 Except as otherwise provided in this chapter, a (1)220 pharmacy licensed under this chapter may perform centralized 221 prescription filling for another pharmacy, provided that the 222 pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the 223 224 responsibilities of each pharmacy, and the manner in which the 225 pharmacies will comply with federal and state laws, rules, and 226 regulations.

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

TITLE AMENDMENT

231 Remove everything before the enacting clause and insert: 232 An act relating to telepharmacy; amending s. 465.003, F.S.; revising and providing definitions; amending s. 465.014, F.S.; 233 234 authorizing a registered pharmacy technician to dispense 235 medicinal drugs under certain conditions; amending s. 465.015, 236 F.S.; conforming provisions to changes made by the act; creating 237 s. 465.0198, F.S.; providing permit requirements for remote dispensing site pharmacies; providing requirements and 238 prohibitions for a remote dispensing site pharmacy; requiring 239 240 the prescription department manager to visit the remote 422357 - h0679-strike.docx

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241 dispensing site pharmacy; providing an experience requirement 242 for a registered pharmacy technician working at a remote site 243 pharmacy; prohibiting a registered pharmacy technician from 244 performing sterile or nonsterile compounding; amending s. 245 465.022, F.S.; authorizing a Florida licensed pharmacist to 246 serve as the prescription drug manager at more than one remote 247 dispensing site pharmacy under certain conditions; amending s. 465.0265, F.S.; conforming provisions to changes made by the 248 249 act; providing an effective date.

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