

By Senator Collins

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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  
10      supervision limitations; amending s. 465.015, F.S.;  
11      providing applicability; exempting certain registered  
12      pharmacy technicians from specified prohibitions;  
13      creating s. 465.0198, F.S.; defining the terms  
14      "supervising pharmacy" and "telepharmacy"; providing  
15      for the permitting of remote-site pharmacies;  
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  
20      pharmacy's prescription department manager within a  
21      specified timeframe; providing requirements for  
22      remote-site pharmacies; authorizing remote-site  
23      pharmacies to store, hold, and dispense medicinal  
24      drugs; prohibiting the dispensing of Schedule II  
25      medications at remote-site pharmacies unless a  
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

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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 Definitions.—As 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  
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

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59 in writing, if in the exercise of her or his professional  
60 judgment counseling is necessary. The actual sales transaction  
61 and delivery of such drug shall not be considered dispensing.  
62 The administration shall not be considered dispensing.

63 (20) (a) "Pharmacy" includes a community pharmacy, an  
64 institutional pharmacy, a nuclear pharmacy, a special pharmacy,  
65 ~~and an Internet pharmacy, and a remote-site pharmacy.~~

66 1. The term "community pharmacy" includes every location  
67 where medicinal drugs are compounded, dispensed, stored, or sold  
68 or where prescriptions are filled or dispensed on an outpatient  
69 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  
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.

81 4. The term "special pharmacy" includes every location  
82 where medicinal drugs are compounded, dispensed, stored, or sold  
83 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  
87 with or obtain information from consumers in this state and use

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88 such communication or information to fill or refill  
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 6. The term "remote-site pharmacy" includes every location  
94 where medicinal drugs are dispensed by a registered pharmacy  
95 technician who is remotely supervised by an offsite pharmacist  
96 acting in the capacity of a prescription department manager.

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

101 1. 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 3. A pharmacist from, ~~or~~ performing any other function for  
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 4. An offsite pharmacist, acting in the capacity of a  
110 prescription department manager, from remotely supervising a  
111 registered pharmacy technician at a remote-site pharmacy.

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

114 465.014 Pharmacy technician.—

115 (1) A person other than a licensed pharmacist or pharmacy  
116 intern may not engage in the practice of the profession of

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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  
120 purview of s. 465.003, and a registered pharmacy technician  
121 operating under remote supervision of an offsite pharmacist  
122 under s. 465.0198 may dispense medicinal drugs under such  
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  
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  
131 pharmacy technician, except as provided in s. 465.0198 or unless  
132 otherwise permitted by the guidelines adopted by the board. The  
133 board shall establish guidelines to be followed by licensees or  
134 permittees in determining the circumstances under which a  
135 licensed pharmacist may supervise more than one pharmacy  
136 technician.

137 Section 3. Paragraph (b) of subsection (1) and paragraph  
138 (b) of subsection (2) of section 465.015, Florida Statutes, are  
139 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:

144 (b) In which a person not licensed as a pharmacist in this  
145 state or not registered as an intern in this state or in which

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146 an intern who is not acting under the direct and immediate  
147 personal supervision of a licensed pharmacist fills, compounds,  
148 or dispenses any prescription or dispenses medicinal drugs. This  
149 paragraph does not apply to any person who owns, operates,  
150 maintains, opens, establishes, conducts, or has charge of a  
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, ~~or~~ 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:

165 (a) "Supervising pharmacy" means a pharmacy licensed in  
166 this state which employs or contracts with a pharmacist licensed  
167 in this state who remotely supervises a registered pharmacy  
168 technician at a remote-site pharmacy at a ratio of one  
169 pharmacist to up to six registered pharmacy technicians.

170 (b) "Telepharmacy" means the practice of pharmacy by a  
171 pharmacist located in this state using telecommunications or  
172 other automations and technologies to provide or supervise the  
173 provision of pharmacy services to patients and their agents who  
174 are located at sites other than where the pharmacist is located,

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175 including dispensing of prescriptions to and counseling of  
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 a  
189 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.

201 2. The procedures for supervising the remote-site pharmacy  
202 and counseling its patients.

203 3. The procedures for reviewing the prescription drug

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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 any  
222 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.

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

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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:

251 465.022 Pharmacies; general requirements; fees.—

252 (11) A permittee must notify the department of the identity  
253 of the prescription department manager within 10 days after  
254 employment. The prescription department manager must comply with  
255 the following requirements:

256 (c) A registered pharmacist may not serve as the  
257 prescription department manager in more than one location,  
258 except as authorized under s. 465.0198, unless approved by the  
259 board.

260 Section 6. This act shall take effect July 1, 2024.