



446160

LEGISLATIVE ACTION

Senate

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House

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The Committee on Health Policy (Stargel) recommended the following:

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

Section 1. Subsections (7) and (13) of section 465.003,  
Florida Statutes, are amended, and subsections (21) and (22) are  
added to that section, to read:

465.003 Definitions.—As used in this chapter, the term:

(7) "Institutional formulary system" means a method whereby  
the medical staff evaluates, appraises, and selects those



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11 medicinal drugs or proprietary preparations which in the medical  
12 staff's clinical judgment are most useful in patient care, and  
13 which are available for dispensing by a practicing pharmacist in  
14 a Class II or Class III institutional pharmacy.

15 (13) "Practice of the profession of pharmacy" includes  
16 compounding, dispensing, and consulting concerning contents,  
17 therapeutic values, and uses of any medicinal drug; consulting  
18 concerning therapeutic values and interactions of patent or  
19 proprietary preparations, whether pursuant to prescriptions or  
20 in the absence and entirely independent of such prescriptions or  
21 orders; and conducting other pharmaceutical services. For  
22 purposes of this subsection, "other pharmaceutical services"  
23 means the monitoring of the patient's drug therapy and assisting  
24 the patient in the management of his or her drug therapy, and  
25 includes review of the patient's drug therapy and communication  
26 with the patient's prescribing health care provider as licensed  
27 under chapter 458, chapter 459, chapter 461, or chapter 466, or  
28 similar statutory provision in another jurisdiction, or such  
29 provider's agent or such other persons as specifically  
30 authorized by the patient, regarding the drug therapy. However,  
31 nothing in this subsection may be interpreted to permit an  
32 alteration of a prescriber's directions, the diagnosis or  
33 treatment of any disease, the initiation of any drug therapy,  
34 the practice of medicine, or the practice of osteopathic  
35 medicine, unless otherwise permitted by law. "Practice of the  
36 profession of pharmacy" also includes any other act, service,  
37 operation, research, or transaction incidental to, or forming a  
38 part of, any of the foregoing acts, requiring, involving, or  
39 employing the science or art of any branch of the pharmaceutical



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40 profession, study, or training, and shall expressly permit a  
41 pharmacist to transmit information from persons authorized to  
42 prescribe medicinal drugs to their patients. The practice of the  
43 profession of pharmacy also includes the administration of  
44 vaccines to adults pursuant to s. 465.189 and the preparation of  
45 prepackaged drug products in facilities holding Class III  
46 institutional pharmacy permits.

47 (21) "Central distribution facility" means a facility under  
48 common control with a hospital holding a Class III institutional  
49 pharmacy permit that may dispense, distribute, compound, or fill  
50 prescriptions for medicinal drugs; prepare prepackaged drug  
51 products; and conduct other pharmaceutical services.

52 (22) "Common control" means the power to direct or cause  
53 the direction of the management and policies of a person or an  
54 organization, whether by ownership of stock, voting rights,  
55 contract, or otherwise.

56 Section 2. Subsection (2) of section 465.004, Florida  
57 Statutes, is amended to read:

58 465.004 Board of Pharmacy.-

59 (2) Seven members of the board must be licensed pharmacists  
60 who are residents of this state and who have been engaged in the  
61 practice of the profession of pharmacy in this state for at  
62 least 4 years and, to the extent practicable, represent the  
63 various pharmacy practice settings. Of the pharmacist members,  
64 two must be currently engaged in the practice of pharmacy in a  
65 community pharmacy, two must be currently engaged in the  
66 practice of pharmacy in a Class II, ~~institutional pharmacy or a~~  
67 Modified Class II, or Class III institutional pharmacy, and  
68 three must be pharmacists licensed in this state irrespective of



69 practice setting. The remaining two members must be residents of  
70 the state who have never been licensed as pharmacists and who  
71 are in no way connected with the practice of the profession of  
72 pharmacy. No person may be appointed as a consumer member who is  
73 in any way connected with a drug manufacturer or wholesaler. At  
74 least one member of the board must be 60 years of age or older.  
75 The Governor shall appoint members to the board in accordance  
76 with this subsection as members' terms expire or as a vacancy  
77 occurs until the composition of the board complies with the  
78 requirements of this subsection.

79 Section 3. Subsections (4) and (6) of section 465.019,  
80 Florida Statutes, are amended, and paragraph (d) is added to  
81 subsection (2) of that section, to read:

82 465.019 Institutional pharmacies; permits.—

83 (2) The following classes of institutional pharmacies are  
84 established:

85 (d)1. "Class III institutional pharmacies" are those  
86 institutional pharmacies, including central distribution  
87 facilities, affiliated with a hospital that provide the same  
88 services that are authorized by a Class II institutional  
89 pharmacy permit. Class III institutional pharmacies may also:

90 a. Dispense, distribute, compound, and fill prescriptions  
91 for medicinal drugs.

92 b. Prepare prepackaged drug products.

93 c. Conduct other pharmaceutical services for the affiliated  
94 hospital and for entities under common control that are each  
95 permitted under this chapter to possess medicinal drugs.

96 d. Provide the services in sub-subparagraphs a.-c. to an  
97 entity under common control which holds an active health care



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98 clinic establishment permit as required under s. 499.01(2)(r).

99 2. A Class III institutional pharmacy shall maintain  
100 policies and procedures addressing:

101 a. The consultant pharmacist responsible for pharmaceutical  
102 services.

103 b. Safe practices for the preparation, dispensing,  
104 prepackaging, distribution, and transportation of medicinal  
105 drugs and prepackaged drug products.

106 c. Recordkeeping to monitor the movement, distribution, and  
107 transportation of medicinal drugs and prepackaged drug products.

108 d. Recordkeeping of pharmacy staff responsible for each  
109 step in the preparation, dispensing, prepackaging,  
110 transportation, and distribution of medicinal drugs and  
111 prepackaged drug products.

112 e. Medicinal drugs and prepackaged drug products that may  
113 not be safely distributed among Class III institutional  
114 pharmacies.

115 (4) Medicinal drugs shall be dispensed in an institutional  
116 pharmacy to outpatients only when that institution has secured a  
117 community pharmacy permit from the department. However, an  
118 individual licensed to prescribe medicinal drugs in this state  
119 may dispense up to a 24-hour supply of a medicinal drug to any  
120 patient of an emergency department of a hospital that operates a  
121 Class II or Class III institutional pharmacy, provided that the  
122 physician treating the patient in such hospital's emergency  
123 department determines that the medicinal drug is warranted and  
124 that community pharmacy services are not readily accessible,  
125 geographically or otherwise, to the patient. Such dispensing  
126 from the emergency department must be in accordance with the



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127 procedures of the hospital. For any such patient for whom a  
128 medicinal drug is warranted for a period to exceed 24 hours, an  
129 individual licensed to prescribe such drug must dispense a 24-  
130 hour supply of such drug to the patient and must provide the  
131 patient with a prescription for such drug for use after the  
132 initial 24-hour period. The board may adopt rules necessary to  
133 carry out the provisions of this subsection.

134 (6) In a Class II or Class III institutional pharmacy, an  
135 institutional formulary system may be adopted with approval of  
136 the medical staff for the purpose of identifying those medicinal  
137 drugs, proprietary preparations, biologics, biosimilars, and  
138 biosimilar interchangeables that may be dispensed by the  
139 pharmacists employed in such institution. A facility with a  
140 Class II or Class III institutional pharmacy permit which is  
141 operating under the formulary system shall establish policies  
142 and procedures for the development of the system in accordance  
143 with the joint standards of the American Hospital Association  
144 and American Society of Hospital Pharmacists for the utilization  
145 of a hospital formulary system, which formulary shall be  
146 approved by the medical staff.

147 Section 4. Subsection (3) of section 465.0252, Florida  
148 Statutes, is amended to read:

149 465.0252 Substitution of interchangeable biosimilar  
150 products.—

151 (3) A pharmacist who practices in a Class II, ~~or~~ Modified  
152 Class II, or Class III institutional pharmacy shall comply with  
153 the notification provisions of paragraph (2) (c) by entering the  
154 substitution in the institution's written medical record system  
155 or electronic medical record system.



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156 Section 5. Subsection (39) of section 499.003, Florida  
157 Statutes, is amended, and paragraphs (w) and (x) are added to  
158 subsection (48) of that section, to read:

159 499.003 Definitions of terms used in this part.—As used in  
160 this part, the term:

161 (39) "Prepackaged drug product" means a drug that  
162 originally was in finished packaged form sealed by a  
163 manufacturer and that is placed in a properly labeled container  
164 by a pharmacy or practitioner authorized to dispense pursuant to  
165 chapter 465 for the purpose of dispensing or by a facility  
166 holding a Class III institutional pharmacy permit in the  
167 establishment in which the prepackaging occurred.

168 (48) "Wholesale distribution" means the distribution of a  
169 prescription drug to a person other than a consumer or patient,  
170 or the receipt of a prescription drug by a person other than the  
171 consumer or patient, but does not include:

172 (w) A hospital covered by s. 340B of the Public Health  
173 Service Act, 42 U.S.C. s. 256b, that arranges for a prescription  
174 drug wholesale distributor to distribute prescription drugs  
175 covered under that act directly to a contract pharmacy. Such  
176 hospital is exempt from obtaining a restricted prescription drug  
177 distributor permit under s. 499.01(2)(h).

178 (x) The dispensing or distribution of a medicinal drug by a  
179 Class III institutional pharmacy pursuant to s. 465.019.

180 Section 6. Paragraphs (b) and (h) of subsection (2) and  
181 subsection (5) of section 499.01, Florida Statutes, are amended  
182 to read:

183 499.01 Permits.—

184 (2) The following permits are established:



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185           (b) *Prescription drug repackager permit.*—A prescription  
186 drug repackager permit is required for any person that  
187 repackages a prescription drug in this state.

188           1. A person that operates an establishment permitted as a  
189 prescription drug repackager may engage in distribution of  
190 prescription drugs repackaged at that establishment and must  
191 comply with all of the provisions of this part and the rules  
192 adopted under this part that apply to a prescription drug  
193 manufacturer.

194           2. A prescription drug repackager must comply with all  
195 appropriate state and federal good manufacturing practices.

196           3. A prescription drug repackager permit is not required  
197 for distributing medicinal drugs or prepackaged drug products  
198 between entities under common control which each hold an active  
199 Class III institutional pharmacy permit under chapter 465 or an  
200 active health care clinic establishment permit under paragraph  
201 (r). For purposes of this subparagraph, the term “common  
202 control” has the same meaning as in s. 499.003(48)(a)3.

203           (h) *Restricted prescription drug distributor permit.*—

204           1. A restricted prescription drug distributor permit is  
205 required for:

206           a. Any person located in this state who engages in the  
207 distribution of a prescription drug, which distribution is not  
208 considered “wholesale distribution” under s. 499.003(48)(a).

209           b. Any person located in this state who engages in the  
210 receipt or distribution of a prescription drug in this state for  
211 the purpose of processing its return or its destruction if such  
212 person is not the person initiating the return, the prescription  
213 drug wholesale supplier of the person initiating the return, or





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214 the manufacturer of the drug.

215 c. A blood establishment located in this state which  
216 collects blood and blood components only from volunteer donors  
217 as defined in s. 381.06014 or pursuant to an authorized  
218 practitioner's order for medical treatment or therapy and  
219 engages in the wholesale distribution of a prescription drug not  
220 described in s. 499.003(48) (j) to a health care entity. A mobile  
221 blood unit operated by a blood establishment permitted under  
222 this sub-subparagraph is not required to be separately  
223 permitted. The health care entity receiving a prescription drug  
224 distributed under this sub-subparagraph must be licensed as a  
225 closed pharmacy or provide health care services at that  
226 establishment. The blood establishment must operate in  
227 accordance with s. 381.06014 and may distribute only:

228 (I) Prescription drugs indicated for a bleeding or clotting  
229 disorder or anemia;

230 (II) Blood-collection containers approved under s. 505 of  
231 the federal act;

232 (III) Drugs that are blood derivatives, or a recombinant or  
233 synthetic form of a blood derivative;

234 (IV) Prescription drugs that are identified in rules  
235 adopted by the department and that are essential to services  
236 performed or provided by blood establishments and authorized for  
237 distribution by blood establishments under federal law; or

238 (V) To the extent authorized by federal law, drugs  
239 necessary to collect blood or blood components from volunteer  
240 blood donors; for blood establishment personnel to perform  
241 therapeutic procedures under the direction and supervision of a  
242 licensed physician; and to diagnose, treat, manage, and prevent



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243 any reaction of a volunteer blood donor or a patient undergoing  
244 a therapeutic procedure performed under the direction and  
245 supervision of a licensed physician,

246  
247 as long as all of the health care services provided by the blood  
248 establishment are related to its activities as a registered  
249 blood establishment or the health care services consist of  
250 collecting, processing, storing, or administering human  
251 hematopoietic stem cells or progenitor cells or performing  
252 diagnostic testing of specimens if such specimens are tested  
253 together with specimens undergoing routine donor testing. The  
254 blood establishment may purchase and possess the drugs described  
255 in this sub-subparagraph without a health care clinic  
256 establishment permit.

257       2. Storage, handling, and recordkeeping of these  
258 distributions by a person required to be permitted as a  
259 restricted prescription drug distributor must be in accordance  
260 with the requirements for wholesale distributors under s.  
261 499.0121.

262       3. A person who applies for a permit as a restricted  
263 prescription drug distributor, or for the renewal of such a  
264 permit, must provide to the department the information required  
265 under s. 499.012.

266       4. The department may adopt rules regarding the  
267 distribution of prescription drugs by hospitals, health care  
268 entities, charitable organizations, other persons not involved  
269 in wholesale distribution, and blood establishments, which rules  
270 are necessary for the protection of the public health, safety,  
271 and welfare.



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272           5. A restricted prescription drug distributor permit is not  
273 required for distributions between pharmacies that each hold an  
274 active permit under chapter 465, have a common ownership, and  
275 are operating in a freestanding end-stage renal dialysis clinic,  
276 if such distributions are made to meet the immediate emergency  
277 medical needs of specifically identified patients and do not  
278 occur with such frequency as to amount to the regular and  
279 systematic supplying of that drug between the pharmacies. The  
280 department shall adopt rules establishing when the distribution  
281 of a prescription drug under this subparagraph amounts to the  
282 regular and systematic supplying of that drug.

283           6. A restricted prescription drug distributor permit is not  
284 required for distributing medicinal drugs or prepackaged drug  
285 products between entities under common control that each hold  
286 either an active Class III institutional pharmacy permit under  
287 chapter 465 or an active health care clinic establishment permit  
288 under paragraph (2) (r). For purposes of this subparagraph, the  
289 term "common control" has the same meaning as in s.  
290 499.003(48) (a) 3.

291           ~~(5) A prescription drug repackager permit issued under this~~  
292 ~~part is not required for a restricted prescription drug~~  
293 ~~distributor permitholder that is a health care entity to~~  
294 ~~repackage prescription drugs in this state for its own use or~~  
295 ~~for distribution to hospitals or other health care entities in~~  
296 ~~the state for their own use, pursuant to s. 499.003(48) (a) 3.,~~  
297 ~~if:~~

298           ~~(a) The prescription drug distributor notifies the~~  
299 ~~department, in writing, of its intention to engage in~~  
300 ~~repackaging under this exemption, 30 days before engaging in the~~



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301 ~~repackaging of prescription drugs at the permitted~~  
302 ~~establishment;~~

303 ~~(b) The prescription drug distributor is under common~~  
304 ~~control with the hospitals or other health care entities to~~  
305 ~~which the prescription drug distributor is distributing~~  
306 ~~prescription drugs. As used in this paragraph, "common control"~~  
307 ~~means the power to direct or cause the direction of the~~  
308 ~~management and policies of a person or an organization, whether~~  
309 ~~by ownership of stock, voting rights, contract, or otherwise;~~

310 ~~(c) The prescription drug distributor repackages the~~  
311 ~~prescription drugs in accordance with current state and federal~~  
312 ~~good manufacturing practices; and~~

313 ~~(d) The prescription drug distributor labels the~~  
314 ~~prescription drug it repackages in accordance with state and~~  
315 ~~federal laws and rules.~~

316  
317 ~~The prescription drug distributor is exempt from the product~~  
318 ~~registration requirements of s. 499.015 with regard to the~~  
319 ~~prescription drugs that it repackages and distributes under this~~  
320 ~~subsection. A prescription drug distributor that repackages and~~  
321 ~~distributes prescription drugs under this subsection to a not-~~  
322 ~~for-profit rural hospital, as defined in s. 395.602, is not~~  
323 ~~required to comply with paragraph (c) or paragraph (d), but must~~  
324 ~~provide to each health care entity for which it repackages, for~~  
325 ~~each prescription drug that is repackaged and distributed, the~~  
326 ~~information required by department rule for labeling~~  
327 ~~prescription drugs. The department shall adopt rules to ensure~~  
328 ~~the safety and integrity of prescription drugs repackaged and~~  
329 ~~distributed under this subsection, including rules regarding~~



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330 ~~prescription drug manufacturing and labeling requirements.~~

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

332

333 ===== T I T L E A M E N D M E N T =====

334 And the title is amended as follows:

335 Delete everything before the enacting clause

336 and insert:

337 A bill to be entitled

338 An act relating to pharmacies; amending s. 465.003,  
339 F.S.; revising and providing definitions; amending s.  
340 465.004, F.S.; revising the membership of the Board of  
341 Pharmacy; amending s. 465.019, F.S.; establishing  
342 Class III institutional pharmacies; providing  
343 requirements for such pharmacies; conforming  
344 provisions to changes made by the act; amending s.  
345 465.0252, F.S.; revising notice requirements to  
346 conform to changes made by the act; amending s.  
347 499.003, F.S.; providing and revising definitions;  
348 amending s. 499.01, F.S.; authorizing the distribution  
349 of medicinal drugs and prepackaged drug products  
350 without a specified permit under certain conditions;  
351 deleting a provision exempting certain drug  
352 repackagers from specified permit requirements;  
353 providing an effective date.