

26 | whereby the medical staff evaluates, appraises, and selects
27 | those medicinal drugs or proprietary preparations which in the
28 | medical staff's clinical judgment are most useful in patient
29 | care, and which are available for dispensing by a practicing
30 | pharmacist in a Class II or Class III institutional pharmacy.

31 | (13) "Practice of the profession of pharmacy" includes
32 | compounding, dispensing, and consulting concerning contents,
33 | therapeutic values, and uses of any medicinal drug; consulting
34 | concerning therapeutic values and interactions of patent or
35 | proprietary preparations, whether pursuant to prescriptions or
36 | in the absence and entirely independent of such prescriptions or
37 | orders; and conducting other pharmaceutical services. For
38 | purposes of this subsection, "other pharmaceutical services"
39 | means the monitoring of the patient's drug therapy and assisting
40 | the patient in the management of his or her drug therapy, and
41 | includes review of the patient's drug therapy and communication
42 | with the patient's prescribing health care provider as licensed
43 | under chapter 458, chapter 459, chapter 461, or chapter 466, or
44 | similar statutory provision in another jurisdiction, or such
45 | provider's agent or such other persons as specifically
46 | authorized by the patient, regarding the drug therapy. However,
47 | nothing in this subsection may be interpreted to permit an
48 | alteration of a prescriber's directions, the diagnosis or
49 | treatment of any disease, the initiation of any drug therapy,
50 | the practice of medicine, or the practice of osteopathic

51 medicine, unless otherwise permitted by law. "Practice of the
52 profession of pharmacy" also includes any other act, service,
53 operation, research, or transaction incidental to, or forming a
54 part of, any of the foregoing acts, requiring, involving, or
55 employing the science or art of any branch of the pharmaceutical
56 profession, study, or training, and shall expressly permit a
57 pharmacist to transmit information from persons authorized to
58 prescribe medicinal drugs to their patients. The practice of the
59 profession of pharmacy also includes the administration of
60 vaccines to adults pursuant to s. 465.189 and the preparation of
61 prepackaged drug products in facilities holding Class III
62 institutional pharmacy permits.

63 (21) "Central distribution facility" means a facility
64 under common control with a hospital holding a Class III
65 institutional pharmacy permit that may dispense, distribute,
66 compound, or fill prescriptions for medicinal drugs; prepare
67 prepackaged drug products; and conduct other pharmaceutical
68 services.

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

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

75 465.004 Board of Pharmacy.—

76 (2) Seven members of the board must be licensed
77 pharmacists who are residents of this state and who have been
78 engaged in the practice of the profession of pharmacy in this
79 state for at least 4 years and, to the extent practicable,
80 represent the various pharmacy practice settings. Of the
81 pharmacist members, two must be currently engaged in the
82 practice of pharmacy in a community pharmacy, two must be
83 currently engaged in the practice of pharmacy in a Class II,
84 ~~institutional pharmacy or a~~ Modified Class II, or Class III
85 institutional pharmacy, and three must be pharmacists licensed
86 in this state irrespective of practice setting. The remaining
87 two members must be residents of the state who have never been
88 licensed as pharmacists and who are in no way connected with the
89 practice of the profession of pharmacy. No person may be
90 appointed as a consumer member who is in any way connected with
91 a drug manufacturer or wholesaler. At least one member of the
92 board must be 60 years of age or older. The Governor shall
93 appoint members to the board in accordance with this subsection
94 as members' terms expire or as a vacancy occurs until the
95 composition of the board complies with the requirements of this
96 subsection.

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

100 465.019 Institutional pharmacies; permits.-

101 (2) The following classes of institutional pharmacies are
102 established:

103 (d)1. "Class III institutional pharmacies" are those
104 institutional pharmacies, including central distribution
105 facilities, affiliated with a hospital that provide the same
106 services that are authorized by a Class II institutional
107 pharmacy permit. Class III institutional pharmacies may also:

108 a. Dispense, distribute, compound, and fill prescriptions
109 for medicinal drugs.

110 b. Prepare prepackaged drug products.

111 c. Conduct other pharmaceutical services for the
112 affiliated hospital and for entities under common control that
113 are each permitted under this chapter to possess medicinal
114 drugs.

115 d. Provide the services in sub-subparagraphs a.-c. to an
116 entity under common control which holds an active health care
117 clinic establishment permit as required under s. 499.01(2)(r).

118 2. A Class III institutional pharmacy shall maintain
119 policies and procedures addressing:

120 a. The consultant pharmacist responsible for
121 pharmaceutical services.

122 b. Safe practices for the preparation, dispensing,
123 prepackaging, distribution, and transportation of medicinal
124 drugs and prepackaged drug products.

125 c. Recordkeeping to monitor the movement, distribution,

126 and transportation of medicinal drugs and prepackaged drug
127 products.

128 d. Recordkeeping of pharmacy staff responsible for each
129 step in the preparation, dispensing, prepackaging,
130 transportation, and distribution of medicinal drugs and
131 prepackaged drug products.

132 e. Medicinal drugs and prepackaged drug products that may
133 not be safely distributed among Class III institutional
134 pharmacies.

135 (4) Medicinal drugs shall be dispensed in an institutional
136 pharmacy to outpatients only when that institution has secured a
137 community pharmacy permit from the department. However, an
138 individual licensed to prescribe medicinal drugs in this state
139 may dispense up to a 24-hour supply of a medicinal drug to any
140 patient of an emergency department of a hospital that operates a
141 Class II or Class III institutional pharmacy, provided that the
142 physician treating the patient in such hospital's emergency
143 department determines that the medicinal drug is warranted and
144 that community pharmacy services are not readily accessible,
145 geographically or otherwise, to the patient. Such dispensing
146 from the emergency department must be in accordance with the
147 procedures of the hospital. For any such patient for whom a
148 medicinal drug is warranted for a period to exceed 24 hours, an
149 individual licensed to prescribe such drug must dispense a 24-
150 hour supply of such drug to the patient and must provide the

151 patient with a prescription for such drug for use after the
152 initial 24-hour period. The board may adopt rules necessary to
153 carry out the provisions of this subsection.

154 (6) In a Class II or Class III institutional pharmacy, an
155 institutional formulary system may be adopted with approval of
156 the medical staff for the purpose of identifying those medicinal
157 drugs, proprietary preparations, biologics, biosimilars, and
158 biosimilar interchangeables that may be dispensed by the
159 pharmacists employed in such institution. A facility with a
160 Class II or Class III institutional pharmacy permit which is
161 operating under the formulary system shall establish policies
162 and procedures for the development of the system in accordance
163 with the joint standards of the American Hospital Association
164 and American Society of Hospital Pharmacists for the utilization
165 of a hospital formulary system, which formulary shall be
166 approved by the medical staff.

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

169 465.0252 Substitution of interchangeable biosimilar
170 products.—

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

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

179 499.003 Definitions of terms used in this part.—As used in
 180 this part, the term:

181 (39) "Prepackaged drug product" means a drug that
 182 originally was in finished packaged form sealed by a
 183 manufacturer and that is placed in a properly labeled container
 184 by a pharmacy or practitioner authorized to dispense pursuant to
 185 chapter 465 for the purpose of dispensing or by a facility
 186 holding a Class III institutional pharmacy permit ~~in the~~
 187 ~~establishment in which the prepackaging occurred.~~

188 (48) "Wholesale distribution" means the distribution of a
 189 prescription drug to a person other than a consumer or patient,
 190 or the receipt of a prescription drug by a person other than the
 191 consumer or patient, but does not include:

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

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

200 Section 6. Paragraphs (b) and (h) of subsection (2) and

201 subsection (5) of section 499.01, Florida Statutes, are amended
 202 to read:

203 499.01 Permits.—

204 (2) The following permits are established:

205 (b) Prescription drug repackager permit.—A prescription
 206 drug repackager permit is required for any person that
 207 repackages a prescription drug in this state.

208 1. A person that operates an establishment permitted as a
 209 prescription drug repackager may engage in distribution of
 210 prescription drugs repackaged at that establishment and must
 211 comply with all of the provisions of this part and the rules
 212 adopted under this part that apply to a prescription drug
 213 manufacturer.

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

216 3. A prescription drug repackager permit is not required
 217 for distributing medicinal drugs or prepackaged drug products
 218 between entities under common control which each hold an active
 219 Class III institutional pharmacy permit under chapter 465 or an
 220 active health care clinic establishment permit under paragraph
 221 (2)(r). For purposes of this subparagraph, the term "common
 222 control" has the same meaning as in s. 499.003(48)(a)3.

223 (h) Restricted prescription drug distributor permit.—

224 1. A restricted prescription drug distributor permit is
 225 required for:

226 a. Any person located in this state who engages in the
227 distribution of a prescription drug, which distribution is not
228 considered "wholesale distribution" under s. 499.003(48)(a).

229 b. Any person located in this state who engages in the
230 receipt or distribution of a prescription drug in this state for
231 the purpose of processing its return or its destruction if such
232 person is not the person initiating the return, the prescription
233 drug wholesale supplier of the person initiating the return, or
234 the manufacturer of the drug.

235 c. A blood establishment located in this state which
236 collects blood and blood components only from volunteer donors
237 as defined in s. 381.06014 or pursuant to an authorized
238 practitioner's order for medical treatment or therapy and
239 engages in the wholesale distribution of a prescription drug not
240 described in s. 499.003(48)(j) to a health care entity. A mobile
241 blood unit operated by a blood establishment permitted under
242 this sub-subparagraph is not required to be separately
243 permitted. The health care entity receiving a prescription drug
244 distributed under this sub-subparagraph must be licensed as a
245 closed pharmacy or provide health care services at that
246 establishment. The blood establishment must operate in
247 accordance with s. 381.06014 and may distribute only:

248 (I) Prescription drugs indicated for a bleeding or
249 clotting disorder or anemia;

250 (II) Blood-collection containers approved under s. 505 of

251 the federal act;

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

254 (IV) Prescription drugs that are identified in rules
255 adopted by the department and that are essential to services
256 performed or provided by blood establishments and authorized for
257 distribution by blood establishments under federal law; or

258 (V) To the extent authorized by federal law, drugs
259 necessary to collect blood or blood components from volunteer
260 blood donors; for blood establishment personnel to perform
261 therapeutic procedures under the direction and supervision of a
262 licensed physician; and to diagnose, treat, manage, and prevent
263 any reaction of a volunteer blood donor or a patient undergoing
264 a therapeutic procedure performed under the direction and
265 supervision of a licensed physician,

266
267 as long as all of the health care services provided by the blood
268 establishment are related to its activities as a registered
269 blood establishment or the health care services consist of
270 collecting, processing, storing, or administering human
271 hematopoietic stem cells or progenitor cells or performing
272 diagnostic testing of specimens if such specimens are tested
273 together with specimens undergoing routine donor testing. The
274 blood establishment may purchase and possess the drugs described
275 in this sub-subparagraph without a health care clinic

276 establishment permit.

277 2. Storage, handling, and recordkeeping of these
278 distributions by a person required to be permitted as a
279 restricted prescription drug distributor must be in accordance
280 with the requirements for wholesale distributors under s.
281 499.0121.

282 3. A person who applies for a permit as a restricted
283 prescription drug distributor, or for the renewal of such a
284 permit, must provide to the department the information required
285 under s. 499.012.

286 4. The department may adopt rules regarding the
287 distribution of prescription drugs by hospitals, health care
288 entities, charitable organizations, other persons not involved
289 in wholesale distribution, and blood establishments, which rules
290 are necessary for the protection of the public health, safety,
291 and welfare.

292 5. A restricted prescription drug distributor permit is
293 not required for distributions between pharmacies that each hold
294 an active permit under chapter 465, have a common ownership, and
295 are operating in a freestanding end-stage renal dialysis clinic,
296 if such distributions are made to meet the immediate emergency
297 medical needs of specifically identified patients and do not
298 occur with such frequency as to amount to the regular and
299 systematic supplying of that drug between the pharmacies. The
300 department shall adopt rules establishing when the distribution

301 of a prescription drug under this subparagraph amounts to the
302 regular and systematic supplying of that drug.

303 6. A restricted prescription drug distributor permit is
304 not required for distributing medicinal drugs or prepackaged
305 drug products between entities under common control that each
306 hold either an active Class III institutional pharmacy permit
307 under chapter 465 or an active health care clinic establishment
308 permit under paragraph (2)(r). For purposes of this
309 subparagraph, the term "common control" has the same meaning as
310 in s. 499.003(48)(a)3.

311 ~~(5) A prescription drug repackager permit issued under~~
312 ~~this part is not required for a restricted prescription drug~~
313 ~~distributor permit holder that is a health care entity to~~
314 ~~repackage prescription drugs in this state for its own use or~~
315 ~~for distribution to hospitals or other health care entities in~~
316 ~~the state for their own use, pursuant to s. 499.003(48)(a)3.,~~
317 ~~if:~~

318 ~~(a) The prescription drug distributor notifies the~~
319 ~~department, in writing, of its intention to engage in~~
320 ~~repackaging under this exemption, 30 days before engaging in the~~
321 ~~repackaging of prescription drugs at the permitted~~
322 ~~establishment;~~

323 ~~(b) The prescription drug distributor is under common~~
324 ~~control with the hospitals or other health care entities to~~
325 ~~which the prescription drug distributor is distributing~~

326 ~~prescription drugs. As used in this paragraph, "common control"~~
327 ~~means the power to direct or cause the direction of the~~
328 ~~management and policies of a person or an organization, whether~~
329 ~~by ownership of stock, voting rights, contract, or otherwise;~~

330 ~~(c) The prescription drug distributor repackages the~~
331 ~~prescription drugs in accordance with current state and federal~~
332 ~~good manufacturing practices; and~~

333 ~~(d) The prescription drug distributor labels the~~
334 ~~prescription drug it repackages in accordance with state and~~
335 ~~federal laws and rules.~~

336
337 ~~The prescription drug distributor is exempt from the product~~
338 ~~registration requirements of s. 499.015 with regard to the~~
339 ~~prescription drugs that it repackages and distributes under this~~
340 ~~subsection. A prescription drug distributor that repackages and~~
341 ~~distributes prescription drugs under this subsection to a not-~~
342 ~~for-profit rural hospital, as defined in s. 395.602, is not~~
343 ~~required to comply with paragraph (c) or paragraph (d), but must~~
344 ~~provide to each health care entity for which it repackages, for~~
345 ~~each prescription drug that is repackaged and distributed, the~~
346 ~~information required by department rule for labeling~~
347 ~~prescription drugs. The department shall adopt rules to ensure~~
348 ~~the safety and integrity of prescription drugs repackaged and~~
349 ~~distributed under this subsection, including rules regarding~~
350 ~~prescription drug manufacturing and labeling requirements.~~

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