

Amendment No.

CHAMBER ACTION

Senate

House

.

Representative Willhite offered the following:

Amendment to Amendment (203208) (with title amendment)

Remove lines 5-51 of the amendment and insert:

Section 1. Subsection (4) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.-

(4) Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, ~~an individual licensed to prescribe medicinal drugs in this state may be dispensed by dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a~~

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

14 hospital that operates a Class II or Class III institutional
15 pharmacy to a patient of the hospital's emergency department or
16 a hospital inpatient upon discharge, if a prescriber provided
17 ~~that the physician~~ treating the patient in such hospital
18 ~~hospital's emergency department~~ determines that the medicinal
19 drug is warranted and that community pharmacy services are not
20 readily accessible, geographically or otherwise, to the patient.
21 Such prescribing and dispensing from the emergency department
22 ~~must be in accordance with the procedures of the hospital. For~~
23 ~~any such patient for whom a medicinal drug is warranted for a~~
24 ~~period to exceed 24 hours, an individual licensed to prescribe~~
25 ~~such drug~~ must be for the greater of dispense a 24-hour supply
26 of such drug or a supply of such drug which must last the
27 patient until the next business day, to the patient and the
28 prescriber must provide the patient with a prescription for such
29 drug for use after such ~~the~~ initial ~~24-hour~~ period. The board
30 may adopt rules necessary to carry out the provisions of this
31 subsection.

32 Section 2. Section 465.0235, Florida Statutes, is amended
33 to read:

34 465.0235 Automated pharmacy systems used by long-term care
35 facilities, hospices, or state correctional institutions or for
36 outpatient dispensing.-

37 (1) A pharmacy may provide pharmacy services to a long-
38 term care facility or hospice licensed under chapter 400 or

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

39 chapter 429 or a state correctional institution operated under
40 chapter 944 through the use of an automated pharmacy system that
41 need not be located at the same location as the pharmacy.

42 (2) A community pharmacy, as defined in s. 465.003 and
43 licensed in this state, may provide pharmacy services for
44 outpatient dispensing through the use of an automated pharmacy
45 system that need not be located at the same location as the
46 community pharmacy if:

47 (a) The automated pharmacy system is under the supervision
48 and control of the community pharmacy.

49 (b) The community pharmacy providing services through the
50 automated pharmacy system notifies the board of the location of
51 the automated pharmacy system and any changes in such location.

52 (c) The automated pharmacy system is under the supervision
53 and control of a pharmacist, as defined in s. 465.003 and
54 licensed in this state, who is available and accessible for
55 patient counseling before the dispensing of any medicinal drug.

56 (d) The automated pharmacy system does not contain or
57 dispense any controlled substances listed in Schedule II,
58 Schedule III, Schedule IV, or Schedule V of s. 893.03 or 21
59 U.S.C. s. 812.

60 (e) The community pharmacy maintains a record of the
61 medicinal drugs dispensed, including the identity of the
62 pharmacist responsible for verifying the accuracy of the dosage
63 and directions and providing patient counseling.

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

64 (f) The automated pharmacy system ensures the
65 confidentiality of personal health information.

66 (3)-(2) Medicinal drugs stored in bulk or unit of use in an
67 automated pharmacy system servicing a long-term care facility,
68 hospice, or correctional institution, or for outpatient
69 dispensing, are part of the inventory of the pharmacy providing
70 pharmacy services to that facility, hospice, or institution, or
71 for outpatient dispensing, and medicinal drugs delivered by the
72 automated pharmacy system are considered to have been dispensed
73 by that pharmacy.

74 (4)-(3) The operation of an automated pharmacy system must
75 be under the supervision of a ~~Florida-licensed~~ pharmacist
76 licensed in this state. To qualify as a supervisor for an
77 automated pharmacy system, the pharmacist need not be physically
78 present at the site of the automated pharmacy system and may
79 supervise the system electronically. The ~~Florida-licensed~~
80 pharmacist shall be required to develop and implement policies
81 and procedures designed to verify that the medicinal drugs
82 delivered by the automated dispensing system are accurate and
83 valid and that the machine is properly restocked.

84 (5)-(4) The Legislature does not intend this section to
85 limit the current practice of pharmacy in this state. This
86 section is intended to allow automated pharmacy systems to
87 enhance the ability of a pharmacist to provide pharmacy services
88 in locations that do not employ a full-time pharmacist. This

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

89 section does not limit or replace the use of a consultant
90 pharmacist.

91 ~~(6)(5)~~ The board shall adopt rules governing the use of ~~an~~
92 automated pharmacy systems ~~system by January 1, 2005~~, which must
93 include specify:

94 (a) Recordkeeping requirements.~~†~~

95 (b) Security requirements.~~†~~ and

96 (c) Labeling requirements that permit the use of unit-dose
97 medications if the facility, hospice, or institution maintains
98 medication-administration records that include directions for
99 use of the medication and the automated pharmacy system

100 identifies:

101 1. The dispensing pharmacy.~~†~~

102 2. The prescription number.~~†~~

103 3. The name of the patient.~~†~~ and

104 4. The name of the prescribing practitioner.

105 Section 3. Section 465.1902, Florida Statutes, is created
106 to read:

107 465.1902 Prescription Drug Donation Repository Program.—

108 (1) SHORT TITLE.—This section may be cited as the

109 "Prescription Drug Donation Repository Program Act."

110 (2) DEFINITIONS.—As used in this section, the term:

111 (a) "Closed drug delivery system" means a system in which

112 the actual control of the unit-dose medication package is

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

113 maintained by the facility, rather than by the individual
114 patient.

115 (b) "Controlled substance" means any substance listed
116 under Schedule II, Schedule III, Schedule IV, or Schedule V of
117 s. 893.03.

118 (c) "Dispenser" means a health care practitioner who,
119 within the scope of his or her practice act, is authorized to
120 dispense medicinal drugs and who does so under this act.

121 (d) "Free clinic" means a clinic that delivers only
122 medical diagnostic services or nonsurgical medical treatment
123 free of charge to low-income recipients.

124 (e) "Health care practitioner" or "practitioner" means a
125 practitioner licensed under this chapter, chapter 458, chapter
126 459, chapter 461, chapter 463, chapter 464, or chapter 466.

127 (f) "Indigent" means having a family income for the 12
128 months preceding the determination of income that is below 200
129 percent of the federal poverty level as defined by the most
130 recently revised poverty income guidelines published by the
131 United States Department of Health and Human Services.

132 (g) "Nonprofit health clinic" means a nonprofit legal
133 entity that provides medical care to patients who are indigent,
134 uninsured, or underinsured. The term includes, but is not
135 limited to, a federally qualified health center as defined in 42
136 U.S.C. s. 1396d(1)(2)(B) and a rural health clinic as defined in
137 42 U.S.C. s. 1396d(1)(1).

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

138 (h) "Nursing home facility" has the same meaning as in s.
139 400.021.

140 (i) "Prescriber" means a health care practitioner who,
141 within the scope of his or her practice act, is authorized to
142 prescribe medicinal drugs.

143 (j) "Prescription drug" has the same meaning as the term
144 "medicinal drugs" or "drugs," as those terms are defined in s.
145 465.003(8), but does not include controlled substances, cancer
146 drugs donated under s. 499.029, or drugs with an approved
147 Federal Food and Drug Administration risk evaluation and
148 mitigation strategy that includes elements to assure safe use.

149 (k) "Program" means the Prescription Drug Donation
150 Repository Program created by this section.

151 (l) "Supply" means a material or an instrument used to
152 administer a prescription drug.

153 (m) "Tamper-evident packaging" means a package that has
154 one or more indicators or barriers to access which, if breached
155 or missing, can reasonably be expected to provide visible
156 evidence to consumers that tampering has occurred. The term
157 includes, but is not limited to, unopened unit-dose packaging,
158 multiple-dose packaging, and medications with a seal on their
159 immediate, outer, secondary, or tertiary packaging.

160 (n) "Underinsured" means having health care coverage or
161 prescription drug coverage, but having exhausted these benefits

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

162 or not having prescription drug coverage for the drug
163 prescribed.

164 (o) "Uninsured" means not having health care coverage and
165 being ineligible for prescription drug coverage under a program
166 funded in whole or in part by the Federal Government.

167 (3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM;
168 CREATION; PURPOSE.—The Prescription Drug Donation Repository
169 Program is created within the department to facilitate the
170 donation of prescription drugs and supplies to eligible
171 patients.

172 (4) REPOSITORIES.—

173 (a) A repository may accept and dispense eligible
174 donations to eligible patients under the program. The repository
175 must inspect, store, and dispense donations and report to the
176 department in accordance with this section.

177 (b) The following entities may participate as a
178 repository:

179 1. A health care practitioner's office.

180 2. A pharmacy.

181 3. A hospital with a closed drug delivery system.

182 4. A nursing home facility with a closed drug delivery
183 system.

184 5. A free clinic or nonprofit health clinic that is
185 licensed or permitted to dispense medicinal drugs in the state.

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

186 (c) An eligible entity must notify the department of its
187 intent to participate in the program as a repository before
188 accepting or dispensing any donations under the program. The
189 notification must be made on a physical or an electronic form
190 prescribed by the department in rule and must, at a minimum,
191 include:

192 1. The name, street address, website, and telephone number
193 of the intended repository and any license or registration
194 number issued by the state to the intended repository, including
195 the name of the issuing agency.

196 2. The name and telephone number of the pharmacist
197 employed by or under contract with the intended repository who
198 is responsible for the inspection of donated prescription drugs
199 and supplies.

200 3. A signed and dated statement by the responsible
201 pharmacist affirming that the intended repository meets the
202 eligibility requirements of this subsection.

203 (d) A repository may withdraw from participation in the
204 program at any time by providing written notice to the
205 department, as appropriate, on a physical or an electronic form
206 prescribed by the department in rule. The department shall adopt
207 rules addressing the disposition of prescription drugs and
208 supplies in the possession of the withdrawing repository.

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

- 209 (5) ELIGIBLE DONORS.—The following entities may donate
210 prescription drugs or supplies to a repository under the
211 program:
- 212 (a) Nursing home facilities with closed drug delivery
213 systems.
- 214 (b) Hospices that have maintained control of a patient's
215 prescription drugs.
- 216 (c) Hospitals with closed drug delivery systems.
- 217 (d) Pharmacies.
- 218 (e) Drug manufacturers or wholesale distributors.
- 219 (f) Medical device manufacturers or suppliers.
- 220 (g) Prescribers who receive prescription drugs or supplies
221 directly from a drug manufacturer, wholesale distributor, or
222 pharmacy.
- 223 (6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED
224 DONATIONS.—
- 225 (a) An eligible donor may only donate a prescription drug
226 to a repository if:
- 227 1. The drug is approved for medical use in the United
228 States.
- 229 2. The drug is in unopened, tamper-evident packaging.
- 230 3. The drug requires storage at normal room temperature
231 per the manufacturer or federal storage requirements.
- 232 4. The drug has been stored according to manufacturer or
233 federal storage requirements.

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

234 5. The drug does not have any physical signs of tampering
235 or adulteration and there is no reason to believe that the drug
236 is adulterated.

237 6. The packaging does not have any physical signs of
238 tampering, misbranding, deterioration, compromised integrity, or
239 adulteration.

240 7. The packaging indicates the expiration date of the
241 drug. If the lot number is not retrievable, all specified
242 medications must be destroyed in the event of a recall.

243 8. The drug has an expiration date that is more than 3
244 months after the date on which the drug was donated.

245 (b) An eligible donor may donate a prescription drug or
246 supply to a repository only if it is in unopened, tamper-evident
247 packaging.

248 (c) Donations must be made on the premises of a repository
249 to a person designated by the repository. A drop box may not be
250 used to accept donations.

251 (d) A prescription drug or supply may not be donated to a
252 specific patient.

253 (7) INSPECTION AND STORAGE.—

254 (a) Upon receipt of a proposed donation, a licensed
255 pharmacist employed by or under contract with a repository shall
256 inspect the donation to determine whether it meets the
257 requirements of subsections (5) and (6). The repository shall

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

258 quarantine a donation until such inspection is complete and the
259 donation is approved for dispensing.

260 (b) The inspecting pharmacist must sign an inspection
261 record on a physical or an electronic form prescribed by the
262 department in rule which verifies that the prescription drug or
263 supply meets the criteria of subsections (5) and (6) and must
264 attach the record to the inventory required by paragraph (d). A
265 repository that receives prescription drugs and supplies from
266 another repository is not required to reinspect such drugs and
267 supplies.

268 (c) A repository shall store donations in a secure storage
269 area under the environmental conditions specified by the
270 manufacturer or federal storage requirements. Donations may not
271 be stored with other inventory.

272 (d) A repository shall maintain an inventory of the name,
273 strength, available quantity, and expiration date of donations;
274 the transaction date; and the name, street address, and
275 telephone number of the donor. The repository shall record such
276 inventory on a physical or an electronic form prescribed by the
277 department in rule.

278 (e) By the 5th day of each month, a repository shall
279 submit to the department its inventory records of donations
280 received during the previous month.

281 (f) The department may facilitate the redistribution of
282 donations between repositories. A repository that receives

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

283 donations may, after notifying the department, distribute the
284 donations to another repository.

285 (8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT
286 NOTICE; PROHIBITIONS.-

287 (a) A repository may dispense an eligible donation to a
288 state resident who is indigent, uninsured, or underinsured, and
289 who has a valid prescription for such donation, as applicable.

290 (b) Each new eligible patient must submit an intake
291 collection form to a repository to receive a donation using a
292 physical or an electronic form prescribed by the department in
293 rule. Such form shall, at a minimum, include:

294 1. The name, street address, and telephone number of the
295 eligible patient.

296 2. The basis for the patient's eligibility, which must
297 specify that the patient is indigent, uninsured, or
298 underinsured.

299 3. A statement physically or electronically signed and
300 dated by the patient affirming that the patient meets the
301 eligibility requirements of this section and will inform the
302 repository if the patient's eligibility changes.

303 4. Notice that the prescription drug or supply was donated
304 to the program, that the donors and participants in the program
305 are immune from civil or criminal liability or disciplinary
306 action, and that the eligible patient is not required to pay for
307 the prescription drug or supply.

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

308 5. A statement physically or electronically signed and
309 dated by the eligible patient acknowledging receipt of notice
310 required under this paragraph.

311 (c) By the 5th day of each month, a repository shall
312 submit to the department a summary of each intake collection
313 form obtained during the previous month.

314 (d) A dispenser may dispense donations, if available, only
315 to an eligible patient who has submitted a completed intake
316 collection form.

317 (e) A dispenser may provide dispensing and consulting
318 services to an eligible patient.

319 (f) Donations may not be sold or resold.

320 (g) A dispenser may not submit a claim or otherwise seek
321 reimbursement from any public or private third-party payor for
322 donations.

323 (9) RECALLED PRESCRIPTION DRUGS.—

324 (a) Each repository shall establish and follow a protocol
325 for notifying recipients in the event that a prescription drug
326 donated under the program is recalled.

327 (b) A repository shall destroy all donated prescription
328 drugs that are recalled, expired, or unsuitable for dispensing.
329 A repository must complete a destruction form for all such drugs
330 using a physical or an electronic form prescribed by the
331 department in rule.

332 (10) RECORDKEEPING.—

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

333 (a) A repository shall maintain records of prescription
334 drugs and supplies that are accepted, donated, dispensed,
335 distributed, or destroyed under the program using a physical or
336 an electronic form prescribed by the department in rule.

337 (b) All required records must be maintained in accordance
338 with any applicable practice act. A repository shall submit
339 these records monthly to the department for data collection.

340 (11) REGISTRIES; PUBLICATION OF FORMS.—

341 (a) The department shall establish and maintain registries
342 of all repositories and of prescription drugs and supplies
343 available under the program. The registry of repositories must
344 include each repository's name, street address, website, and
345 telephone number. The registry of available prescription drugs
346 and supplies must include the name, strength, available
347 quantity, and expiration date of the prescription drugs or
348 supplies and the name and contact information of each repository
349 where such drugs or supplies are available. The department shall
350 publish the registries on its website.

351 (b) The department shall publish all forms required by
352 this section on its website.

353 (12) IMMUNITY FROM LIABILITY; DISCIPLINARY ACTION.—

354 (a) Any donor of prescription drugs or supplies and any
355 participant in the program who exercises reasonable care in
356 donating, accepting, distributing, or dispensing prescription
357 drugs or supplies under the program is immune from civil or

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

358 criminal liability and from professional disciplinary action by
359 the state for any injury, death, or loss to person or property
360 relating to such activities.

361 (b) A pharmaceutical manufacturer who exercises reasonable
362 care is not liable for any claim or injury arising from the
363 donation of any prescription drug or supply under this section,
364 including, but not limited to, liability for failure to transfer
365 or communicate product or consumer information regarding the
366 donated prescription drug or supply, including its expiration
367 date.

368 (13) RULEMAKING.—The department shall adopt rules
369 necessary to administer this section.

370 Section 4. Paragraph (o) is added to subsection (5) of
371 section 252.36, Florida Statutes, to read:

372 252.36 Emergency management powers of the Governor.—

373 (5) In addition to any other powers conferred upon the
374 Governor by law, she or he may:

375 (o) Waive the patient eligibility requirements of s.
376 465.1902.

377 Section 5. For the 2019-2020 fiscal year, two full-time
378 equivalent positions with associated salary rate of 150,449 are
379 authorized and the sums of \$325,423 in recurring funds and
380 \$78,233 in nonrecurring funds from the Grants and Donations
381 Trust Fund are appropriated to the Department of Health for the

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

382 purpose of implementing s. 465.1902, Florida Statutes, as
383 created by this act.

384 -----
385
386 **T I T L E A M E N D M E N T**

387 Remove lines 60-70 of the amendment and insert:
388 amending s. 465.019, F.S.; authorizing certain
389 individuals to prescribe and dispense a limited supply
390 of medicinal drugs to any patient of an emergency
391 department of a hospital or a patient discharged from
392 a hospital under certain circumstances; amending s.
393 465.0235, F.S.; authorizing a community pharmacy to
394 use an automated pharmacy system under certain
395 circumstances; providing that certain medicinal drugs
396 stored in such system for outpatient dispensing are
397 part of the inventory of the pharmacy providing
398 services through such system; requiring the Board of
399 Pharmacy to adopt rules; creating s. 465.1902, F.S.;
400 providing a short title; defining terms; creating the
401 Prescription Drug Donation Repository Program within
402 the Department of Health; specifying the purpose of
403 the program; specifying entities that may participate
404 as repositories; requiring a repository to notify the
405 department of its intent to participate in the
406 program; providing notification requirements;

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

407 providing a procedure for a repository to withdraw
408 from participation in the program; requiring the
409 department to adopt rules regarding the disposition of
410 prescription drugs and supplies of a withdrawing
411 repository; specifying entities that may donate
412 prescription drugs or supplies under the program;
413 providing criteria and procedures for eligible
414 donations; prohibiting donations to specific patients;
415 providing inspection, inventory, and storage
416 requirements for repositories; requiring inspection of
417 donated prescription drugs and supplies by a licensed
418 pharmacist; requiring a repository to submit its
419 inventory records to the department monthly;
420 authorizing the department to facilitate the
421 redistribution of donations of prescription drugs or
422 supplies; authorizing a repository to transfer
423 prescription drugs or supplies to another repository
424 after notifying the department; specifying patients
425 eligible to receive donated prescription drugs and
426 supplies; specifying conditions for dispensing donated
427 prescription drugs and supplies to eligible patients;
428 providing intake collection form requirements;
429 requiring that such form provide certain notice to
430 patients; prohibiting the sale of donated prescription
431 drugs and supplies under the program; requiring

489627

Approved For Filing: 5/1/2019 4:08:00 PM

Amendment No.

432 repositories to establish a protocol for notifying
433 recipients of a prescription drug recall; providing
434 for destruction of donated prescription drugs under
435 certain circumstances; providing recordkeeping
436 requirements; requiring the department to establish,
437 maintain, and publish a registry of participating
438 repositories and available donated prescription drugs
439 and supplies; requiring the department to publish
440 certain information and forms on its website;
441 providing immunity from civil and criminal liability
442 and from professional disciplinary action for donors
443 and participants under certain circumstances;
444 providing immunity to pharmaceutical manufacturers,
445 under certain circumstances, from any claim or injury
446 arising from the donation of any prescription drug or
447 supply under the program; requiring the department to
448 adopt rules; amending s. 252.36, F.S.; authorizing the
449 Governor to waive program patient eligibility
450 requirements during a declared state of emergency;
451 authorizing positions and providing appropriations;
452 providing an effective date.

489627

Approved For Filing: 5/1/2019 4:08:00 PM