

1                                   A bill to be entitled  
2           An act relating to the Prescription Drug Donation  
3           Repository Program; creating s. 465.1902, F.S.;  
4           providing a short title; creating the Prescription  
5           Drug Donation Repository Program within the Department  
6           of Health; providing purpose; authorizing the  
7           department to contract with a third party to implement  
8           and administer the program; providing definitions;  
9           specifying entities that are eligible donors;  
10          providing criteria for eligible donations; prohibiting  
11          donations to a specific patient; providing for certain  
12          prescription drugs that are eligible for return to be  
13          credited to Medicaid under specified conditions;  
14          prohibiting the donation of certain drugs pursuant to  
15          federal restrictions; authorizing repositories to  
16          refuse to accept donations of prescription drugs or  
17          supplies; providing inspection, inventory, and storage  
18          requirements for centralized and local repositories;  
19          requiring inspection of donated prescription drugs and  
20          supplies by a licensed pharmacist; requiring a local  
21          repository to notify the centralized repository within  
22          a specified timeframe after receiving a donation of  
23          prescription drugs or supplies; authorizing a  
24          centralized repository to redistribute prescription  
25          drugs or supplies; requiring local repositories to

26 | notify the department regarding participation in the  
 27 | program; providing conditions for dispensing donated  
 28 | prescription drugs and supplies to eligible patients;  
 29 | requiring repositories to establish a protocol for  
 30 | notifying recipients of a prescription drug recall;  
 31 | providing for destruction of donated prescription  
 32 | drugs in the event of a drug recall; providing  
 33 | recordkeeping requirements; requiring the department  
 34 | to maintain and publish a registry of participating  
 35 | local repositories and available donated prescription  
 36 | drugs and supplies; providing immunity from civil and  
 37 | criminal liability for participants under certain  
 38 | circumstances; requiring the department to adopt  
 39 | rules; amending s. 252.36, F.S.; authorizing the  
 40 | Governor to waive the patient eligibility requirements  
 41 | of s. 465.1902, F.S., during a declared state of  
 42 | emergency; providing an effective date.

44 | Be It Enacted by the Legislature of the State of Florida:

46 | Section 1. Section 465.1902, Florida Statutes, is created  
 47 | to read:

48 | 465.1902 Prescription Drug Donation Repository Program.-

49 | (1) SHORT TITLE.-This section may be cited as the  
 50 | "Prescription Drug Donation Repository Program Act."

51        (2) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM.—There  
52 is created a Prescription Drug Donation Repository Program  
53 within the Department of Health for the purpose of authorizing  
54 and facilitating the donation of prescription drugs and supplies  
55 to eligible patients. The department may contract with a third  
56 party to implement and administer the program.

57        (3) DEFINITIONS.—As used in this section, the term:

58        (a) "Centralized repository" means a distributor permitted  
59 pursuant to chapter 499 which is approved by the department or  
60 the contractor to accept, inspect, inventory, and distribute  
61 donated drugs and supplies under this section.

62        (b) "Closed drug delivery system" means a system in which  
63 the actual control of the unit-dose medication package is  
64 maintained by the facility rather than by the individual  
65 patient.

66        (c) "Contractor" means the third-party vendor approved by  
67 the department to implement and administer the program.

68        (d) "Controlled substance" means any substance listed  
69 under Schedule II, Schedule III, Schedule IV, or Schedule V of  
70 s. 893.03.

71        (e) "Department" means Department of Health.

72        (f) "Dispenser" means a dispensing health care  
73 practitioner or pharmacist licensed to dispense medicinal drugs  
74 in the state.

75 (g) "Donor" means an entity that meets the requirements of  
76 subsection (4).

77 (h) "Eligible patient" means a Florida resident who is  
78 indigent, uninsured, or underinsured and has a valid  
79 prescription for a prescription drug or supply that is eligible  
80 for dispensing under the program.

81 (i) "Free clinic" means a clinic that delivers only  
82 medical diagnostic services or nonsurgical medical treatment  
83 free of charge to all low-income recipients.

84 (j) "Health care practitioner" or "practitioner" means a  
85 practitioner licensed under chapter 458, chapter 459, chapter  
86 461, chapter 463, chapter 464, chapter 465, or chapter 466.

87 (k) "Indigent" means a person with an income that is below  
88 200 percent of the federal poverty level as defined by the most  
89 recently revised poverty income guidelines published by the  
90 United States Department of Health and Human Services.

91 (l) "Local repository" means a health care practitioner's  
92 office, pharmacy, hospital with a closed drug delivery system,  
93 nursing home facility with a closed drug delivery system, free  
94 clinic, or nonprofit health clinic that is licensed or permitted  
95 to dispense medicinal drugs in the state.

96 (m) "Nonprofit health clinic" means a nonprofit legal  
97 entity that provides medical care to patients who are indigent,  
98 uninsured, or underinsured, including, but not limited to, a  
99 federally qualified health center as defined in 42 U.S.C. s.

100 1396d(1)(2)(B) and a rural health clinic as defined in 42 U.S.C.  
101 s. 1396d(1)(1).

102 (n) "Nursing home facility" has the same meaning as in s.  
103 400.021(12).

104 (o) "Prescriber" means a prescribing physician,  
105 prescribing practitioner, or other health care practitioner  
106 authorized by the laws of this state to prescribe medicinal  
107 drugs.

108 (p) "Prescription drug" has the same meaning as defined in  
109 s. 465.003(8), but does not include controlled substances or  
110 cancer drugs donated under s. 499.029.

111 (q) "Program" means the Prescription Drug Donation  
112 Repository Program created by this section.

113 (r) "Supplies" means any supply used in the administration  
114 of a prescription drug.

115 (s) "Tamper-evident packaging" means a package that has  
116 one or more indicators or barriers to entry which, if breached  
117 or missing, can reasonably be expected to provide visible  
118 evidence to consumers that tampering has occurred.

119 (t) "Underinsured" means a person who has third-party  
120 insurance or is eligible to receive prescription drugs or  
121 supplies through the Medicaid program or any other prescription  
122 drug program funded in whole or in part by the Federal  
123 Government, but has exhausted these benefits or does not have  
124 prescription drug coverage for the drug prescribed.

125 (u) "Uninsured" means a person who has no third-party  
 126 insurance and is not eligible to receive prescription drugs or  
 127 supplies through the Medicaid program or any other prescription  
 128 drug program funded in whole or in part by the Federal  
 129 Government.

130 (4) DONOR ELIGIBILITY.—The program may only accept a  
 131 donation of a prescription drug or supply from:

132 (a) Nursing home facilities.

133 (b) Hospices.

134 (c) Hospitals with closed drug delivery systems.

135 (d) Pharmacies.

136 (e) Drug manufacturers or wholesale distributors.

137 (f) Medical device manufacturers or suppliers.

138 (g) Prescribers who receive prescription drugs or supplies  
 139 directly from a drug manufacturer, wholesale distributor, or  
 140 pharmacy.

141 (5) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR  
 142 DONATION.—

143 (a) All prescription drugs and supplies that have been  
 144 approved for medical use in the United States and meet the  
 145 criteria for donation established by this section may be  
 146 accepted for donation under the program.

147 (b) The centralized repository or a local repository may  
 148 accept a prescription drug only if:

149        1. The drug is in its original sealed and tamper-evident  
150 packaging. Single-unit-dose drugs may be accepted if the single-  
151 unit-dose packaging is unopened.

152        2. The drug requires storage at normal room temperature  
153 per the manufacturer or the United States Pharmacopeia.

154        3. The drug has been stored according to manufacturer or  
155 United States Pharmacopeia storage requirements.

156        4. The drug does not have any physical signs of tampering  
157 or adulteration and there is no reason to believe that the drug  
158 is adulterated.

159        5. The packaging does not have any physical signs of  
160 tampering, misbranding, deterioration, compromised integrity or  
161 adulteration.

162        6. The packaging contains the lot number and expiration  
163 date of the drug. If the lot number is not retrievable, all  
164 specified medications must be destroyed in the event of a  
165 recall.

166        7. The drug has an expiration date that is more than 3  
167 months after the date that the drug was donated.

168        (c) The central repository or a local repository may  
169 accept supplies that are in their original, unopened, sealed  
170 packaging and have not been adulterated or misbranded.

171        (d) Prescription drugs and supplies may be donated on the  
172 premises of the centralized repository or a local repository to

173 a person designated by the repository. A drop box may not be  
174 used to accept donations.

175 (e) Prescription drugs or supplies may not be donated to a  
176 specific patient.

177 (f) Prescription drugs billed to and paid for by Medicaid  
178 in long-term care facilities that are eligible for return to  
179 stock under federal Medicaid regulations shall be credited to  
180 Medicaid and are not eligible for donation under the program.

181 (g) Prescriptions drugs that are subject to a Federal Food  
182 and Drug Administration Risk Evaluation and Mitigation Strategy  
183 with Elements to Assure Safe Use are not eligible for donation  
184 under the program.

185 (h) Nothing in this section requires the central  
186 repository or a local repository to accept a donation of a  
187 prescription drug or supplies.

188 (6) INSPECTION AND STORAGE.—

189 (a) A licensed pharmacist employed by or under contract  
190 with the centralized repository or a local repository shall  
191 inspect donated prescription drugs and supplies to determine  
192 whether the donated prescription drugs or supplies:

- 193 1. Are eligible for donation under the program;
- 194 2. Have been adulterated or misbranded; and
- 195 3. Are safe and suitable for dispensing.

196 (b) The pharmacist who inspects the donated prescription  
197 drugs or supplies shall sign an inspection record verifying that



198 the criteria of paragraph (a) have been met and attach such  
199 record to the copy of the inventory record. If a local  
200 repository receives drugs and supplies from the centralized  
201 repository, the local repository does not need to reinspect the  
202 drugs and supplies.

203 (c) The centralized repository and local repositories  
204 shall store donated prescription drugs and supplies in a secure  
205 storage area under the environmental conditions specified by the  
206 manufacturer or United States Pharmacopeia for the prescription  
207 drugs or supplies being stored. Donated prescription drugs and  
208 supplies may not be stored with nondonated inventory. A local  
209 repository shall quarantine any donated prescription drugs or  
210 supplies from all dispensing stock until the donated  
211 prescription drugs or supplies are inspected and approved for  
212 dispensing under the program.

213 (d) A local repository shall maintain an inventory of all  
214 donated prescription drugs or supplies it receives. Such  
215 inventory shall be recorded on a form prescribed by the  
216 department and adopted in rule.

217 (e) A local repository shall notify the centralized  
218 repository within 5 days after receipt of any donation of  
219 prescription drugs or supplies to the program. The notification  
220 shall be on a form prescribed by the department and adopted in  
221 rule.

222       (f) The centralized repository shall maintain an inventory  
223 of all prescription drugs and supplies donated to the program.

224       (g) The centralized repository may redistribute  
225 prescription drugs and supplies to facilitate dispensing as  
226 needed.

227       (7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.—

228       (a) A local repository must notify the department of its  
229 intent to participate in the program before accepting or  
230 dispensing any prescription drugs or supplies pursuant to this  
231 section. The notification shall be on a form prescribed by the  
232 department and adopted in rule and must, at a minimum, include:

233           1. The name, street address, and telephone number of the  
234 local repository and any state-issued license or registration  
235 number issued to the local repository, including the name of the  
236 issuing agency.

237           2. The name and telephone number of the pharmacist  
238 employed by or under contract with the local repository who is  
239 responsible for the inspection of donated prescription drugs and  
240 supplies.

241           3. A statement signed and dated by the responsible  
242 pharmacist affirming that the local repository meets the  
243 eligibility requirements of this section.

244       (b) A local repository may withdraw from participation in  
245 the program at any time by providing written notice to the

246 department or contractor on a form prescribed by the department  
247 and adopted in rule.

248 (8) DISPENSING.—

249 (a) Each eligible patient without a program identification  
250 card must submit an intake collection form to a local repository  
251 before receiving prescription drugs or supplies under the  
252 program. The form shall be prescribed by the department and  
253 adopted in rule and shall, at a minimum, include:

254 1. The name, street address, and telephone number of the  
255 eligible patient.

256 2. The basis for eligibility, which must specify that the  
257 patient is indigent, uninsured, or underinsured.

258 3. A statement signed and dated by the eligible patient  
259 affirming that he or she meets the eligibility requirements of  
260 this section.

261 (b) A local repository shall collect a signed and dated  
262 intake collection form from each eligible patient receiving  
263 prescription drugs or supplies under the program. The local  
264 repository shall issue a program identification card upon  
265 receipt of a duly executed intake collection form. The program  
266 identification card shall be valid for 1 year after issuance and  
267 be in a form prescribed by the department and adopted in rule.

268 (c) A local repository shall send a summary of the intake  
269 collection form data to the centralized pharmacy within 5 days  
270 after receipt of a duly executed intake collection form.

271 (d) A dispenser shall only dispense a donated prescription  
272 drug or supplies, if available, to an eligible patient with a  
273 program identification card or a duly executed intake collection  
274 form.

275 (e) A dispenser shall inspect the donated prescription  
276 drugs or supplies prior to dispensing such drugs or supplies.

277 (f) A dispenser may provide dispensing and consulting  
278 services to an eligible patient.

279 (g) Donated prescription drugs and supplies may not be  
280 resold under this program.

281 (h) A dispenser of donated prescription drugs or supplies  
282 may not submit a claim or otherwise seek reimbursement from any  
283 public or private third-party payor for donated prescription  
284 drugs or supplies dispensed to any patient under this program.  
285 However, a repository may charge a handling fee, established by  
286 department rule, for the preparation and dispensing of  
287 prescription drugs or supplies under the program.

288 (i) A local repository that receives donated prescription  
289 drugs or supplies may, with authorization from the centralized  
290 repository, distribute the prescription drugs or supplies to  
291 another local repository.

292 (9) RECALL AND DESTRUCTION OF PRESCRIPTION DRUGS AND  
293 SUPPLIES.—

294 (a) The centralized repository and a local repository  
295 shall be responsible for drug recalls and shall have an

296 established protocol to notify recipients in the event of a  
297 prescription drug recall.

298 (b) Local repositories shall perform a uniform destruction  
299 of all of the recalled prescription drugs in the repository and  
300 complete the destruction information form for all donated  
301 prescription drugs destroyed.

302 (c) Local repositories shall destroy donated prescription  
303 drugs that are not suitable for dispensing and make a record of  
304 such destruction.

305 (10) RECORDKEEPING.—

306 (a) Local repositories shall maintain records of  
307 prescription drugs and supplies that were accepted, donated,  
308 dispensed, distributed, or destroyed under the program.

309 (b) All records required to be maintained as a part of the  
310 program shall be maintained in accordance with any applicable  
311 practice acts. Local repositories shall submit these records  
312 quarterly to the centralized repository for data collection and  
313 the centralized repository shall submit these records and the  
314 collected data in annual reports to the department.

315 (11) REGISTRIES AND FORMS.—

316 (a) The department shall establish and maintain registries  
317 of all local repositories and available drugs and supplies under  
318 the program. The registry of local repositories shall include  
319 the repository's name, address, and telephone number. The  
320 registry of available drugs and supplies shall include the name,

321 strength, available quantity, and expiration date of the drug or  
322 supply and the name and contact information of the repositories  
323 where such drug or supply is available. The department shall  
324 publish the registries on its website.

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

327 (12) IMMUNITY.—

328 (a) Any donor of prescription drugs or supplies, or any  
329 participant in the program, who exercises reasonable care in  
330 donating, accepting, distributing, or dispensing prescription  
331 drugs or supplies under the program, and the rules adopted  
332 pursuant thereto, shall be immune from civil or criminal  
333 liability and from professional disciplinary action of any kind  
334 for any injury, death, or loss to person or property relating to  
335 such activities.

336 (b) A pharmaceutical manufacturer who exercises reasonable  
337 care is not liable for any claim or injury arising from the  
338 transfer of any prescription drug under this section, including  
339 but not limited to, liability for failure to transfer or  
340 communicate product or consumer information regarding the  
341 transferred drug, including the expiration date of the  
342 transferred drug.

343 (13) RULEMAKING.—The department shall adopt rules  
344 necessary to implement the requirements of this section.

345 Section 2. Paragraph (o) is added to subsection (5) of

346 | section 252.36, Florida Statutes, to read:

347 |       252.36 Emergency management powers of the Governor.—

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

350 |       (o) Waive the patient eligibility requirements of s.  
351 | 465.1902.

352 |       Section 3. This act shall take effect July 1, 2018.