

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; defining terms; creating the  
5           Prescription Drug Donation Repository Program within  
6           the Department of Health; specifying the purpose of  
7           the program; specifying entities that may participate  
8           as repositories; requiring a repository to notify the  
9           department of its intent to participate in the  
10          program; providing notification requirements;  
11          providing a procedure for a repository to withdraw  
12          from participation in the program; requiring the  
13          department to adopt rules regarding the disposition of  
14          prescription drugs and supplies of a withdrawing  
15          repository; specifying entities that may donate  
16          prescription drugs or supplies under the program;  
17          providing criteria and procedures for eligible  
18          donations; prohibiting donations to specific patients;  
19          providing inspection, inventory, and storage  
20          requirements for repositories; requiring inspection of  
21          donated prescription drugs and supplies by a licensed  
22          pharmacist; requiring a repository to submit its  
23          inventory records to the department monthly;  
24          authorizing the department to facilitate the  
25          redistribution of donations of prescription drugs or

26 supplies; authorizing a repository to transfer  
27 prescription drugs or supplies to another repository  
28 after notifying the department; specifying patients  
29 eligible to receive donated prescription drugs and  
30 supplies; specifying conditions for dispensing donated  
31 prescription drugs and supplies to eligible patients;  
32 providing intake collection form requirements;  
33 requiring that such form provide certain notice to  
34 patients; prohibiting the sale of donated prescription  
35 drugs and supplies under the program; requiring  
36 repositories to establish a protocol for notifying  
37 recipients of a prescription drug recall; providing  
38 for destruction of donated prescription drugs under  
39 certain circumstances; providing recordkeeping  
40 requirements; requiring the department to establish,  
41 maintain, and publish a registry of participating  
42 repositories and available donated prescription drugs  
43 and supplies; requiring the department to publish  
44 certain information and forms on its website;  
45 providing immunity from civil and criminal liability  
46 and from professional disciplinary action for donors  
47 and participants under certain circumstances;  
48 providing immunity to pharmaceutical manufacturers,  
49 under certain circumstances, from any claim or injury  
50 arising from the donation of any prescription drug or

51 supply under the program; requiring the department to  
 52 adopt rules; amending s. 252.36, F.S.; authorizing the  
 53 Governor to waive program patient eligibility  
 54 requirements during a declared state of emergency;  
 55 authorizing positions and providing appropriations;  
 56 providing an effective date.

57

58 Be It Enacted by the Legislature of the State of Florida:

59

60 Section 1. Section 465.1902, Florida Statutes, is created  
 61 to read:

62 465.1902 Prescription Drug Donation Repository Program.-

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

65 (2) DEFINITIONS.-As used in this section, the term:

66 (a) "Closed drug delivery system" means a system in which  
 67 the actual control of the unit-dose medication package is  
 68 maintained by the facility, rather than by the individual  
 69 patient.

70 (b) "Controlled substance" means any substance listed  
 71 under Schedule II, Schedule III, Schedule IV, or Schedule V of  
 72 s. 893.03.

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

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

79        (e) "Health care practitioner" or "practitioner" means a  
80 practitioner licensed under this chapter, chapter 458, chapter  
81 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

87        (g) "Nonprofit health clinic" means a nonprofit legal  
88 entity that provides medical care to patients who are indigent,  
89 uninsured, or underinsured. The term includes, but is not  
90 limited to, a federally qualified health center as defined in 42  
91 U.S.C. s. 1396d(1) (2) (B) and a rural health clinic as defined in  
92 42 U.S.C. s. 1396d(1) (1).

93        (h) "Nursing home facility" has the same meaning as in s.  
94 400.021.

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

98        (j) "Prescription drug" has the same meaning as the term  
99 "medicinal drugs" or "drugs," as those terms are defined in s.  
100 465.003(8), but does not include controlled substances, cancer

101 drugs donated under s. 499.029, or drugs with an approved  
 102 Federal Food and Drug Administration risk evaluation and  
 103 mitigation strategy that includes elements to assure safe use.

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

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

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

115 (n) "Underinsured" means having health care coverage or  
 116 prescription drug coverage, but having exhausted these benefits  
 117 or not having prescription drug coverage for the drug  
 118 prescribed.

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

122 (3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM;  
 123 CREATION; PURPOSE.—The Prescription Drug Donation Repository  
 124 Program is created within the department to facilitate the  
 125 donation of prescription drugs and supplies to eligible

126 patients.

127 (4) REPOSITORIES.—

128 (a) A repository may accept and dispense eligible  
129 donations to eligible patients under the program. The repository  
130 must inspect, store, and dispense donations and report to the  
131 department in accordance with this section.

132 (b) The following entities may participate as a  
133 repository:

134 1. A health care practitioner's office.

135 2. A pharmacy.

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

137 4. A nursing home facility with a closed drug delivery  
138 system.

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

141 (c) An eligible entity must notify the department of its  
142 intent to participate in the program as a repository before  
143 accepting or dispensing any donations under the program. The  
144 notification must be made on a physical or an electronic form  
145 prescribed by the department in rule and must, at a minimum,  
146 include:

147 1. The name, street address, website, and telephone number  
148 of the intended repository and any license or registration  
149 number issued by the state to the intended repository, including  
150 the name of the issuing agency.

151        2. The name and telephone number of the pharmacist  
152 employed by or under contract with the intended repository who  
153 is responsible for the inspection of donated prescription drugs  
154 and supplies.

155        3. A signed and dated statement by the responsible  
156 pharmacist affirming that the intended repository meets the  
157 eligibility requirements of this subsection.

158        (d) A repository may withdraw from participation in the  
159 program at any time by providing written notice to the  
160 department, as appropriate, on a physical or an electronic form  
161 prescribed by the department in rule. The department shall adopt  
162 rules addressing the disposition of prescription drugs and  
163 supplies in the possession of the withdrawing repository.

164        (5) ELIGIBLE DONORS.—The following entities may donate  
165 prescription drugs or supplies to a repository under the  
166 program:

167        (a) Nursing home facilities with closed drug delivery  
168 systems.

169        (b) Hospices that have maintained control of a patient's  
170 prescription drugs.

171        (c) Hospitals with closed drug delivery systems.

172        (d) Pharmacies.

173        (e) Drug manufacturers or wholesale distributors.

174        (f) Medical device manufacturers or suppliers.

175        (g) Prescribers who receive prescription drugs or supplies

176 directly from a drug manufacturer, wholesale distributor, or  
177 pharmacy.

178 (6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED  
179 DONATIONS.—

180 (a) An eligible donor may only donate a prescription drug  
181 to a repository if:

182 1. The drug is approved for medical use in the United  
183 States.

184 2. The drug is in unopened, tamper-evident packaging.

185 3. The drug requires storage at normal room temperature  
186 per the manufacturer or federal storage requirements.

187 4. The drug has been stored according to manufacturer or  
188 federal storage requirements.

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

192 6. The packaging does not have any physical signs of  
193 tampering, misbranding, deterioration, compromised integrity, or  
194 adulteration.

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

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

200 (b) An eligible donor may donate a prescription drug or

201 supply to a repository only if it is in unopened, tamper-evident  
202 packaging.

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

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

208 (7) INSPECTION AND STORAGE.—

209 (a) Upon receipt of a proposed donation, a licensed  
210 pharmacist employed by or under contract with a repository shall  
211 inspect the donation to determine whether it meets the  
212 requirements of subsections (5) and (6). The repository shall  
213 quarantine a donation until such inspection is complete and the  
214 donation is approved for dispensing.

215 (b) The inspecting pharmacist must sign an inspection  
216 record on a physical or an electronic form prescribed by the  
217 department in rule which verifies that the prescription drug or  
218 supply meets the criteria of subsections (5) and (6) and must  
219 attach the record to the inventory required by paragraph (d). A  
220 repository that receives prescription drugs and supplies from  
221 another repository is not required to reinspect such drugs and  
222 supplies.

223 (c) A repository shall store donations in a secure storage  
224 area under the environmental conditions specified by the  
225 manufacturer or federal storage requirements. Donations may not

226 be stored with other inventory.

227 (d) A repository shall maintain an inventory of the name,  
228 strength, available quantity, and expiration date of donations;  
229 the transaction date; and the name, street address, and  
230 telephone number of the donor. The repository shall record such  
231 inventory on a physical or an electronic form prescribed by the  
232 department in rule.

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

236 (f) The department may facilitate the redistribution of  
237 donations between repositories. A repository that receives  
238 donations may, after notifying the department, distribute the  
239 donations to another repository.

240 (8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT  
241 NOTICE; PROHIBITIONS.—

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

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

249 1. The name, street address, and telephone number of the  
250 eligible patient.

251       2. The basis for the patient's eligibility, which must  
252 specify that the patient is indigent, uninsured, or  
253 underinsured.

254       3. A statement physically or electronically signed and  
255 dated by the patient affirming that the patient meets the  
256 eligibility requirements of this section and will inform the  
257 repository if the patient's eligibility changes.

258       4. Notice that the prescription drug or supply was donated  
259 to the program, that the donors and participants in the program  
260 are immune from civil or criminal liability or disciplinary  
261 action, and that the eligible patient is not required to pay for  
262 the prescription drug or supply.

263       5. A statement physically or electronically signed and  
264 dated by the eligible patient acknowledging receipt of notice  
265 required under this paragraph.

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

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

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

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

275       (g) A dispenser may not submit a claim or otherwise seek

276 reimbursement from any public or private third-party payor for  
277 donations.

278 (9) RECALLED PRESCRIPTION DRUGS.—

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

282 (b) A repository shall destroy all donated prescription  
283 drugs that are recalled, expired, or unsuitable for dispensing.  
284 A repository must complete a destruction form for all such drugs  
285 using a physical or an electronic form prescribed by the  
286 department in rule.

287 (10) RECORDKEEPING.—

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

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

295 (11) REGISTRIES; PUBLICATION OF FORMS.—

296 (a) The department shall establish and maintain registries  
297 of all repositories and of prescription drugs and supplies  
298 available under the program. The registry of repositories must  
299 include each repository's name, street address, website, and  
300 telephone number. The registry of available prescription drugs

301 and supplies must include the name, strength, available  
302 quantity, and expiration date of the prescription drugs or  
303 supplies and the name and contact information of each repository  
304 where such drugs or supplies are available. The department shall  
305 publish the registries on its website.

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

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

309 (a) Any donor of prescription drugs or supplies and any  
310 participant in the program who exercises reasonable care in  
311 donating, accepting, distributing, or dispensing prescription  
312 drugs or supplies under the program is immune from civil or  
313 criminal liability and from professional disciplinary action by  
314 the state for any injury, death, or loss to person or property  
315 relating to such activities.

316 (b) A pharmaceutical manufacturer who exercises reasonable  
317 care is not liable for any claim or injury arising from the  
318 donation of any prescription drug or supply under this section,  
319 including, but not limited to, liability for failure to transfer  
320 or communicate product or consumer information regarding the  
321 donated prescription drug or supply, including its expiration  
322 date.

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

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

326 | section 252.36, Florida Statutes, to read:

327 |       252.36 Emergency management powers of the Governor.—

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

330 |       (o) Waive the patient eligibility requirements of s.  
331 | 465.1902.

332 |       Section 3. For the 2019-2020 fiscal year, two full-time  
333 | equivalent positions with associated salary rate of 150,449 are  
334 | authorized and the sums of \$325,423 in recurring funds and  
335 | \$78,233 in nonrecurring funds from the Grants and Donations  
336 | Trust Fund are appropriated to the Department of Health for the  
337 | purpose of implementing the requirements of this act.

338 |       Section 4. This act shall take effect July 1, 2019.