

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 donated prescription drugs and

26 supplies; authorizing a repository to transfer  
27 prescription drugs and 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 professional disciplinary action for program  
47 donors and participants under certain circumstances;  
48 providing specified immunity to pharmaceutical  
49 manufacturers under certain circumstances; requiring  
50 the department to adopt rules; amending s. 252.36,

51 F.S.; authorizing the Governor to waive program  
 52 patient eligibility requirements during a declared  
 53 state of emergency; authorizing positions and  
 54 providing appropriations; providing an effective date.  
 55

56 Be It Enacted by the Legislature of the State of Florida:  
 57

58 Section 1. Section 465.1902, Florida Statutes, is created  
 59 to read:

60 465.1902 Prescription Drug Donation Repository Program.-

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

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

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

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

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

74 (d) "Free clinic" means a clinic that delivers only  
 75 medical diagnostic services or nonsurgical medical treatment

76 free of charge to low-income recipients.

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

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

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

91 (h) "Nursing home facility" has the same meaning as in s.  
92 400.021.

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

96 (j) "Prescription drug" has the same meaning as the term  
97 "medicinal drugs" or "drugs," as those terms are defined in s.  
98 465.003(8), but does not include controlled substances, cancer  
99 drugs donated under s. 499.029, or drugs with an approved United  
100 States Food and Drug Administration risk evaluation and

101 mitigation strategy that includes elements to assure safe use.

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

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

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

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

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

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

125 (4) REPOSITORIES.—

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

130        (b) The following entities may participate as a  
131 repository:

132            1. A health care practitioner's office.

133            2. A pharmacy.

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

135            4. A nursing home facility with a closed drug delivery  
136 system.

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

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

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

149            2. The name and telephone number of the pharmacist  
150 employed by or under contract with the intended repository who

151 is responsible for the inspection of donated prescription drugs  
152 and supplies.

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

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

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

165 (a) Nursing home facilities with closed drug delivery  
166 systems.

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

169 (c) Hospitals with closed drug delivery systems.

170 (d) Pharmacies.

171 (e) Drug manufacturers or wholesale distributors.

172 (f) Medical device manufacturers or suppliers.

173 (g) Prescribers who receive prescription drugs or supplies  
174 directly from a drug manufacturer, wholesale distributor, or  
175 pharmacy.

176 (6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED  
 177 DONATIONS.—

178 (a) An eligible donor may only donate a prescription drug  
 179 to a repository if:

180 1. The drug is approved for medical use in the United  
 181 States.

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

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

185 4. The drug has been stored according to manufacturer or  
 186 federal storage requirements.

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

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

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

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

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



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

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

206 (7) INSPECTION AND STORAGE.—

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

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

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

225 (d) A repository shall maintain an inventory of the name,

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

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

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

238 (8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT  
239 NOTICE; PROHIBITIONS.—

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

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

247 1. The name, street address, and telephone number of the  
248 eligible patient.

249 2. The basis for the patient's eligibility, which must  
250 specify that the patient is indigent, uninsured, or

251 underinsured.

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

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

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

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

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

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

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

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

276 (9) RECALLED PRESCRIPTION DRUGS.—

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

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

285 (10) RECORDKEEPING.—

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

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

293 (11) REGISTRIES; PUBLICATION OF FORMS.—

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

301 supplies and the name and contact information of each repository  
 302 where such drugs or supplies are available. The department shall  
 303 publish the registries on its website.

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

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

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

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

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

323 Section 2. Paragraph (o) is added to subsection (5) of  
 324 section 252.36, Florida Statutes, to read:

325 252.36 Emergency management powers of the Governor.—

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

328 (o) Waive the patient eligibility requirements of s.  
329 465.1902.

330 Section 3. For the 2020-2021 fiscal year, two full-time  
331 equivalent positions with associated salary rate of 150,449 are  
332 authorized and the sums of \$325,423 in recurring funds and  
333 \$78,233 in nonrecurring funds from the Grants and Donations  
334 Trust Fund are appropriated to the Department of Health for the  
335 purpose of implementing the requirements of this act.

336 Section 4. This act shall take effect July 1, 2020.