

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	—	(Y/N)
ADOPTED AS AMENDED	—	(Y/N)
ADOPTED W/O OBJECTION	—	(Y/N)
FAILED TO ADOPT	—	(Y/N)
WITHDRAWN	—	(Y/N)
OTHER	_____	

1 Committee/Subcommittee hearing bill: Health Quality  
 2 Subcommittee

3 Representative Yarborough offered the following:

**Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 465.1902, Florida Statutes, is created  
 8 to read:

9 465.1902 Prescription Drug Donation Repository Program.--

10 (1) This section may be cited as the "Prescription Drug  
 11 Donation Repository Program Act."

12 (2) There is created a Prescription Drug Donation  
 13 Repository Program within the Department of Health for the  
 14 purpose of authorizing and facilitating the donation of  
 15 prescription drugs and supplies to eligible patients. The

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16 department may contract with a third party to implement and  
17 administer the program.

18 (3) DEFINITIONS.--As used in this section:

19 (a) "Centralized repository" means a distributor permitted  
20 pursuant to chapter 499 approved by the department or the  
21 contractor to accept, inspect, inventory and distribute donated  
22 drugs and supplies under this section.

23 (b) "Closed drug delivery system" means a system in which  
24 the actual control of the unit-dose medication package is  
25 maintained by the facility rather than by the individual  
26 patient.

27 (c) "Contractor" means the third party vendor approved by  
28 the department to implement and administer the Prescription Drug  
29 Donation Repository Program.

30 (d) "Controlled substance" means any substance listed  
31 under Schedule II, Schedule III, Schedule IV, or Schedule V of  
32 s. 893.03

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

34 (f) "Dispenser" means a dispensing health care  
35 practitioner or pharmacist licensed to dispense medicinal drugs  
36 in this state.

37 (g) "Donor" means an entity that meets the requirements of  
38 s. 465.1902(4).

39 (h) "Eligible patient" means a Florida resident who is  
40 indigent, uninsured or underinsured, and has a valid

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41 prescription for a prescription drug or supply eligible for  
42 dispensing under the program.

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

46 (j) "Health care practitioner" or "practitioner" means any  
47 practitioner licensed under chapter 458, chapter 459, chapter  
48 461, chapter 463, chapter 464, chapter 465, or chapter 466.

49 (k) "Indigent" means a person with an income that is below  
50 200 percent of the federal poverty level as defined by the most  
51 recently revised poverty income guidelines published by the  
52 United States Department of Health and Human Services.

53 (l) "Local repository" means a health care practitioner's  
54 office, pharmacy, hospital with a closed drug delivery system,  
55 nursing home facility with a closed drug delivery system, free  
56 clinic or nonprofit health clinic, that is licensed or permitted  
57 to dispense medicinal drugs in this state.

58 (m) "Nonprofit health clinic" means a nonprofit legal  
59 entity that provides medical care to patients who are indigent,  
60 uninsured, or underinsured including, but not limited to, a  
61 federally qualified health center as defined in 42 U.S.C. §  
62 1396d(1) (2) (B) and a rural health clinic as defined in 42 U.S.C.  
63 § 1396d(1) (1).

64 (n) "Nursing home facility" has the same meaning as  
65 defined in s. 400.021(12).

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66 (o) "Prescriber" means a prescribing physician,  
67 prescribing practitioner, or other health care practitioner  
68 authorized by the laws of this state to prescribe medicinal  
69 drugs.

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

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

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

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

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

87 (u) "Uninsured" means a person who has no third-party  
88 insurance and is not eligible to receive prescription drugs or  
89 supplies through the Medicaid program or any other prescription

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90 drug program funded in whole or in part by the Federal  
91 Government.

92 (4) DONOR ELIGIBILITY.--The program may only accept a  
93 donation of a prescription drug or supply from:

94 (a) Nursing home facilities.

95 (b) Hospices.

96 (c) Hospitals with closed drug delivery systems.

97 (d) Pharmacies.

98 (e) Drug manufacturers or wholesale distributors.

99 (f) Medical device manufacturers or suppliers.

100 (g) Prescribers who receive prescription drugs or supplies  
101 directly from a drug manufacturer, wholesale distributor,  
102 or pharmacy.

103 (5) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR  
104 DONATION.--

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

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

111 1. The drug is in its original sealed and tamper-evident  
112 packaging. Single-unit dose drugs may be accepted if the single-  
113 unit-dose packaging is unopened;

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114 2. The drug requires storage at normal room temperature  
115 per the manufacturer or the United States Pharmacopeia;

116 3. The drug has been stored according to manufacturer or  
117 United States Pharmacopeia storage requirements;

118 4. The drug does not have any physical signs of tampering  
119 or adulteration, and there is no reason to believe that the drug  
120 is adulterated;

121 5. The packaging does not have any physical signs of  
122 tampering, misbranding, deterioration, compromised integrity or  
123 adulteration;

124 6. The packaging contains the lot number and expiration  
125 date of the drug. If the lot number is not retrievable, all  
126 specified medications will be destroyed in the event of a  
127 recall; and

128 7. The drug has an expiration date that is more than three  
129 months after the date that the drug was donated.

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

133 (d) Prescription drugs and supplies may be donated on the  
134 premises of the centralized repository or a local repository to  
135 a person designated by the repository. A drop box may not be  
136 used to accept donations.

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

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

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

147 (h) Nothing in this section requires the central  
148 repository or a local repository to accept a donation of a  
149 prescription drug or supply.

150 (6) INSPECTION AND STORAGE.--

151 (a) A licensed pharmacist employed by or under contract  
152 with the centralized repository or a local repository shall  
153 inspect donated prescription drugs and supplies to determine  
154 whether the donated prescription drugs or supplies:

- 155 1. Are eligible for donation under the program;
- 156 2. Have been adulterated or misbranded; and
- 157 3. Are safe and suitable for dispensing.

158 (b) The pharmacist who inspects the donated prescription  
159 drugs or supplies shall sign an inspection record stating the  
160 above and attach it to the copy of the inventory record. If a  
161 local repository receives drugs and supplies from the  
162 centralized repository, the local repository does not need to  
163 re-inspect the drugs and supplies.

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164       (c) The centralized repository and local repositories  
165 shall store donated prescription drugs and supplies in a secure  
166 storage area under the environmental conditions specified by the  
167 manufacturer or United States Pharmacopeia for the prescription  
168 drugs or supplies being stored. Donated prescription drugs and  
169 supplies may not be stored with non-donated inventory. A local  
170 repository shall quarantine from all dispensing stock any  
171 donated prescription drugs or supplies until the donated  
172 prescription drugs or supplies are inspected and approved for  
173 dispensing under the program.

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

178       (e) A local repository shall notify the centralized  
179 repository within 5 days of receipt of any donation of  
180 prescription drugs or supplies to the program. The notification  
181 shall be on a form prescribed by the department and adopted in  
182 rule.

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

185       (g) The centralized repository may redistribute drugs and  
186 supplies to facilitate dispensing as needed.

187       (7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.--



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188 (a) A local repository must notify the department of its  
189 intent to participate in the program prior to accepting or  
190 dispensing any prescription drugs or supplies pursuant to this  
191 section. The notification shall be on a form prescribed by the  
192 department and adopted in rule and must, at a minimum, include:

193 1. The name, street address, and telephone number of the  
194 local repository, and any state-issued license or registration  
195 number issued to the local repository, including the name of the  
196 issuing agency.

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

201 3. A statement signed and dated by the responsible  
202 pharmacist affirming that the local repository meets the  
203 eligibility requirements of this section.

204 (b) A local repository may withdraw from participation in  
205 the program at any time by providing written notice to the  
206 department or contractor on a form prescribed by the department  
207 and adopted in rule.

208 (8) DISPENSING.--

209 (a) Each eligible patient without a program identification  
210 card must submit an intake collection form to a local repository  
211 prior to receiving prescription drugs or supplies under the

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212 program. The form shall be prescribed by the department and  
213 adopted in rule and shall, at a minimum, include:

214 1. The name, street address, and telephone number of the  
215 eligible patient;

216 2. The specific basis for eligibility, which must be  
217 indigent, uninsured or underinsured;

218 3. A statement signed and dated by the eligible patient  
219 affirming that he or she meets the eligibility requirements of  
220 this section.

221 (b) A local repository shall collect a signed and dated  
222 intake collection form from each eligible patient receiving  
223 prescription drugs or supply under the program. The local  
224 repository shall issue a program identification card upon  
225 receipt of a duly executed intake collection form. The program  
226 identification card shall be valid for one year after issuance  
227 and be in a form prescribed by the department and adopted in  
228 rule.

229 (c) A local repository shall send a summary of the intake  
230 collection form data to the centralized pharmacy within 5 days  
231 of receipt of a duly executed intake collection form.

232 (d) A dispenser shall only dispense a donated prescription  
233 drug or supply, if available, to an eligible patient with a  
234 program identification card or a duly executed intake collection  
235 form.

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236 (e) A dispenser shall inspect the donated prescription  
237 drugs or supplies prior to dispensing.

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

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

242 (h) A dispenser of donated prescription drugs or supplies  
243 may not submit a claim or otherwise seek reimbursement from any  
244 public or private third-party payor for donated prescription  
245 drugs or supplies dispensed to any patient under this program.  
246 However, a repository may charge a handling fee, established by  
247 department rule, for the preparation and dispensing of  
248 prescription drugs or supplies under the program.

249 (i) A local repository that receives donated prescription  
250 drugs or supplies may, with authorization from the centralized  
251 repository, distribute the prescription drugs or supplies to  
252 another local repository.

253 (9) RECALL AND DESTRUCTION OF PRESCRIPTION DRUGS AND  
254 SUPPLIES.--

255 (a) The centralized repository and a local repository  
256 shall be responsible for drug recalls and shall have an  
257 established protocol to notify recipients in the event of a  
258 prescription drug recall.

259 (b) Local repositories shall perform a uniform destruction  
260 of all of the recalled prescription drugs in the repository and

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261 complete the destruction information form for all donated  
262 prescription drugs destroyed.

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

266 (10) RECORDKEEPING.--

267 (a) Local repositories shall maintain records of  
268 prescription drugs and supplies that were accepted, donated,  
269 dispensed, distributed or destroyed under this program.

270 (b) All records required to be maintained as a part of  
271 this program shall be maintained in accordance with any  
272 applicable practice acts. Local repositories shall submit these  
273 records quarterly to the centralized repository for data  
274 collection and the centralized repository shall submit these  
275 records and the collected data in annual reports to the  
276 department.

277 (11) REGISTRIES AND FORMS.--

278 (a) The department shall establish and maintain registries  
279 of all local repositories and available drugs and supplies under  
280 the program. The registry of local repositories shall include  
281 the repository's name, address, and telephone number. The  
282 registry of available drugs and supplies shall include the drug  
283 or supply's name, strength, available quantity, and expiration  
284 date, as well as the name and contact information of the

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285 repositories where the drug or supply is available. The  
286 department shall publish the registries on its website.

287 (b) The department shall publish all forms required by  
288 this section on its website

289 (12) IMMUNITY.--

290 (a) Any donor of prescription drugs or supplies, or any  
291 participant in the program, who exercises reasonable care in  
292 donating, accepting, distributing, or dispensing prescription  
293 drugs or supplies under this program, and the rules adopted  
294 pursuant to, shall be immune from civil or criminal liability  
295 and from professional disciplinary action of any kind for any  
296 injury, death, or loss to person or property relating to such  
297 activities.

298 (b) A pharmaceutical manufacturer who exercises reasonable  
299 care is not liable for any claim or injury arising from the  
300 transfer of any prescription drug under this section, including  
301 but not limited to, liability for failure to transfer or  
302 communicate product or consumer information regarding the  
303 transferred drug, as well as the expiration date of the  
304 transferred drug.

305 (13) RULEMAKING.--The department shall adopt rules  
306 necessary to implement the requirements of this section.

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

309 252.36 Emergency management powers of the Governor.-

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

312 (o) Waive the patient eligibility requirements of s.  
313 465.1902.

314 Section 3. This act shall take effect on July 1, 2018.  
315

316 -----  
317 **T I T L E A M E N D M E N T**

318 Remove everything before the enacting clause and insert:  
319 An act relating to the Prescription Drug Donation Repository  
320 Program; creating s. 465.1902, F.S.; providing a short title;  
321 creating the Prescription Drug Donation Repository Program  
322 within the Department of Health; authorizing the donation of  
323 prescription drug and supplies to eligible patients; providing  
324 definitions; providing conditions for eligible donors; providing  
325 conditions for eligible donations; providing inspection and  
326 storage requirements; providing conditions of participation for  
327 local repositories; providing conditions for dispensing donated  
328 prescription drugs and supplies to eligible patients; providing  
329 conditions in the event of a drug recall for donated  
330 prescription drugs; providing recordkeeping requirements;  
331 requiring the department to maintain and publish a registry of  
332 participating local repositories and available donated  
333 prescription drugs and supplies; providing immunity for  
334 participants in certain circumstances; requiring the department

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COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 291 (2018)

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335 | to adopt rules; amending s. 252.36(5), F.S.; authorizing the  
336 | Governor to waive patient eligibility requirements during a  
337 | declared state of emergency; providing an effective date.