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LEGISLATIVE ACTION

Senate

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House

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Floor: NC/2R

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02/12/2020 01:53 PM

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Senator Book moved the following:

**Senate Amendment (with title amendment)**

Delete everything after the enacting clause  
and insert:

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

465.1902 Prescription Drug Donation Repository Program.—

(1) SHORT TITLE.—This section may be cited as the  
“Prescription Drug Donation Repository Program Act.”

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

(a) “Closed drug delivery system” means a system in which



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12 the actual control of the unit-dose medication package is  
13 maintained by the facility, rather than by the individual  
14 patient.

15 (b) "Controlled substance" means any substance listed in  
16 Schedule II, Schedule III, Schedule IV, or Schedule V of s.  
17 893.03.

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

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

24 (e) "Health care practitioner" or "practitioner" means a  
25 practitioner licensed under this chapter, chapter 458, chapter  
26 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

32 (g) "Nonprofit health clinic" means a nonprofit legal  
33 entity that provides medical care to patients who are indigent,  
34 uninsured, or underinsured. The term includes, but is not  
35 limited to, a federally qualified health center as defined in 42  
36 U.S.C. s. 1396d(1) (2) (B) and a rural health clinic as defined in  
37 42 U.S.C. s. 1396d(1) (1).

38 (h) "Nursing home facility" has the same meaning as in s.  
39 400.021.

40 (i) "Prescriber" means a health care practitioner who,



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41 within the scope of his or her practice act, is authorized to  
42 prescribe medicinal drugs.

43 (j) "Prescription drug" has the same meaning as the terms  
44 "medicinal drugs" or "drugs," as those terms are defined in s.  
45 465.003(8), but does not include controlled substances, cancer  
46 drugs donated under s. 499.029, or drugs with an approved United  
47 States Food and Drug Administration risk evaluation and  
48 mitigation strategy that includes elements to assure safe use.

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

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

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

60 (n) "Underinsured" means having health care coverage or  
61 prescription drug coverage, but having exhausted these benefits  
62 or not having prescription drug coverage for the drug  
63 prescribed.

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

67 (3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM;  
68 CREATION; PURPOSE.—The Prescription Drug Donation Repository  
69 Program is created within the department to facilitate the



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70 donation of prescription drugs and supplies to eligible  
71 patients.

72 (4) REPOSITORIES.—

73 (a) A repository may accept and dispense eligible donations  
74 to eligible patients under the program. The repository must  
75 inspect, store, and dispense donations and report to the  
76 department in accordance with this section.

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

78 1. A health care practitioner's office.

79 2. A pharmacy.

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

81 4. A nursing home facility with a closed drug delivery  
82 system.

83 5. A free clinic or nonprofit health clinic that is  
84 licensed or permitted to dispense medicinal drugs in this state.

85 (c) An eligible entity must notify the department of its  
86 intent to participate in the program as a repository before  
87 accepting or dispensing any donations under the program. The  
88 notification must be made on a physical or an electronic form  
89 prescribed by the department in rule and must, at a minimum,  
90 include:

91 1. The name, street address, website, and telephone number  
92 of the intended repository and any license or registration  
93 number issued by the state to the intended repository, including  
94 the name of the issuing agency.

95 2. The name and telephone number of the pharmacist employed  
96 by or under contract with the intended repository who is  
97 responsible for the inspection of donated prescription drugs and  
98 supplies.



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99           3. A signed and dated statement by the responsible  
100 pharmacist affirming that the intended repository meets the  
101 eligibility requirements of this subsection.

102           (d) A repository may withdraw from participation in the  
103 program at any time by providing written notice to the  
104 department, as appropriate, on a physical or an electronic form  
105 prescribed by department rule. The department shall adopt rules  
106 addressing the disposition of prescription drugs and supplies in  
107 the possession of the withdrawing repository.

108           (5) ELIGIBLE DONORS.—The following entities may donate  
109 prescription drugs or supplies to a repository under the  
110 program:

111           (a) Nursing home facilities with closed drug delivery  
112 systems.

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

115           (c) Hospitals with closed drug delivery systems.

116           (d) Pharmacies.

117           (e) Drug manufacturers or wholesale distributors.

118           (f) Medical device manufacturers or suppliers.

119           (g) Prescribers who receive prescription drugs or supplies  
120 directly from a drug manufacturer, wholesale distributor, or  
121 pharmacy.

122           (6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED  
123 DONATIONS.—

124           (a) An eligible donor may donate a prescription drug to a  
125 repository only if:

126           1. The drug is approved for medical use in the United  
127 States.



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- 128        2. The drug is in unopened, tamper-evident packaging.
- 129        3. The drug requires storage at normal room temperature per  
130 the manufacturer or federal storage requirements.
- 131        4. The drug has been stored according to manufacturer or  
132 federal storage requirements.
- 133        5. The drug does not have any physical signs of tampering  
134 or adulteration and there is no reason to believe that the drug  
135 is adulterated.
- 136        6. The packaging does not have any physical signs of  
137 tampering, misbranding, deterioration, compromised integrity, or  
138 adulteration.
- 139        7. The packaging indicates the expiration date of the drug.  
140 All specified medications must be destroyed in the event of a  
141 recall if the lot number is not retrievable.
- 142        8. The drug has an expiration date that is more than 3  
143 months after the date on which the drug was donated.
- 144        (b) An eligible donor may donate a prescription drug or  
145 supply to a repository only if it is in unopened, tamper-evident  
146 packaging.
- 147        (c) Donations must be made on the premises of a repository  
148 to a person designated by the repository. A drop box may not be  
149 used to accept donations.
- 150        (d) A prescription drug or supply may not be donated to a  
151 specific patient.
- 152        (7) INSPECTION AND STORAGE.—
- 153        (a) Upon receipt of a proposed donation, a licensed  
154 pharmacist employed by or under contract with a repository shall  
155 inspect the donation to determine whether it meets the  
156 requirements of subsections (5) and (6). The repository shall



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157 quarantine a donation until such inspection is complete and the  
158 donation is approved for dispensing.

159 (b) If a donation is approved for dispensing, the  
160 inspecting pharmacist shall sign an inspection record on a  
161 physical or an electronic form prescribed by the department in  
162 rule which verifies that the prescription drug or supply meets  
163 the criteria of subsections (5) and (6) and shall attach the  
164 record to the inventory required in paragraph (d). A repository  
165 that receives prescription drugs and supplies from another  
166 repository is not required to reinspect such drugs and supplies.

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

171 (d) A repository shall maintain an inventory of the name,  
172 strength, available quantity, and expiration date of donations;  
173 the transaction date; and the name, street address, and  
174 telephone number of the donor. The repository shall record such  
175 inventory on a physical or an electronic form prescribed by  
176 department rule.

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

180 (f) The department may facilitate the redistribution of  
181 donations between repositories. A repository that receives  
182 donations may, after notifying the department, distribute the  
183 donations to another repository.

184 (8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT  
185 NOTICE; PROHIBITIONS.-



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

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

193           1. The name, street address, and telephone number of the  
194 eligible patient.

195           2. The basis for the patient's eligibility, which must  
196 specify that the patient is indigent, uninsured, or  
197 underinsured.

198           3. A statement physically or electronically signed and  
199 dated by the patient affirming that the patient meets the  
200 eligibility requirements of this section and will inform the  
201 repository if the patient's eligibility changes.

202           4. Notice that the prescription drug or supply was donated  
203 to the program, that the donors and participants in the program  
204 are immune from civil or criminal liability or disciplinary  
205 action, and that the eligible patient is not required to pay for  
206 the prescription drug or supply.

207           5. A statement physically or electronically signed and  
208 dated by the eligible patient acknowledging receipt of notice  
209 required under this paragraph.

210       (c) By the 5th day of each month, a repository shall submit  
211 to the department a summary of each intake collection form  
212 received during the previous month.

213       (d) A dispenser may dispense donations, if available, only  
214 to an eligible patient who has submitted a completed intake





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215 collection form.

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

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

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

222 (9) RECALLED PRESCRIPTION DRUGS.—

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

226 (b) A repository shall destroy all donated prescription  
227 drugs that are recalled, expired, or unsuitable for dispensing.  
228 A repository shall complete a destruction form for all such  
229 drugs using a physical or an electronic form prescribed by the  
230 department in rule.

231 (10) RECORDKEEPING.—

232 (a) A repository shall maintain records of prescription  
233 drugs and supplies that are accepted, donated, dispensed,  
234 distributed, or destroyed under the program using a physical or  
235 an electronic form prescribed by department rule.

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

239 (11) REGISTRIES; PUBLICATION OF FORMS.—

240 (a) The department shall establish and maintain registries  
241 of all repositories and prescription drugs and supplies  
242 available under the program. The registry of repositories must  
243 include each repository's name, street address, website, and



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244 telephone number. The registry of available prescription drugs  
245 and supplies must include the name, strength, available  
246 quantity, and expiration date of the prescription drugs or  
247 supplies and the name and contact information of each repository  
248 where such drugs or supplies are available. The department shall  
249 publish the registries on its website.

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

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

253 (a) Any donor of prescription drugs or supplies and any  
254 participant in the program who exercises reasonable care in  
255 donating, accepting, distributing, or dispensing prescription  
256 drugs or supplies under the program is immune from civil or  
257 criminal liability and professional disciplinary action by the  
258 state for any injury, death, or loss to person or property  
259 relating to such activities.

260 (b) A pharmaceutical manufacturer who exercises reasonable  
261 care is not liable for any claim or injury arising from the  
262 donation of any prescription drug or supply under this section,  
263 including, but not limited to, liability for failure to transfer  
264 or communicate product or consumer information regarding the  
265 donated prescription drug or supply, including its expiration  
266 date.

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

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

271 252.36 Emergency management powers of the Governor.—

272 (5) In addition to any other powers conferred upon the



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273 Governor by law, she or he may:

274 (o) Waive the patient eligibility requirements of s.  
275 465.1902.

276 Section 3. This act shall take effect July 1, 2020.

277

278 ===== T I T L E A M E N D M E N T =====

279 And the title is amended as follows:

280 Delete everything before the enacting clause  
281 and insert:

282 A bill to be entitled  
283 An act relating to the Prescription Drug Donation  
284 Repository Program; creating s. 465.1902, F.S.;  
285 providing a short title; defining terms; creating the  
286 Prescription Drug Donation Repository Program within  
287 the Department of Health; specifying the purpose of  
288 the program; specifying entities that may participate  
289 as repositories; requiring a repository to notify the  
290 department of its intent to participate in the  
291 program; providing notification requirements;  
292 providing a procedure for a repository to withdraw  
293 from participation in the program; requiring the  
294 department to adopt rules regarding the disposition of  
295 prescription drugs and supplies of a withdrawing  
296 repository; specifying entities that may donate  
297 prescription drugs or supplies under the program;  
298 providing criteria and procedures for eligible  
299 donations; prohibiting donations to specific patients;  
300 providing inspection, inventory, and storage  
301 requirements for repositories; requiring inspection of



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302 donated prescription drugs and supplies by a licensed  
303 pharmacist; requiring a repository to submit its  
304 inventory records to the department monthly;  
305 authorizing the department to facilitate the  
306 redistribution of donated prescription drugs and  
307 supplies; authorizing a repository to transfer  
308 prescription drugs and supplies to another repository  
309 after notifying the department; specifying patients  
310 eligible to receive donated prescription drugs and  
311 supplies; specifying conditions for dispensing donated  
312 prescription drugs and supplies to eligible patients;  
313 providing intake collection form requirements;  
314 requiring that such form provide certain notice to  
315 patients; prohibiting the sale of donated prescription  
316 drugs and supplies under the program; prohibiting  
317 dispensers from seeking reimbursement from public or  
318 private third-party payors for donations dispensed  
319 under the program; requiring repositories to establish  
320 a protocol for notifying recipients of a prescription  
321 drug recall; providing for destruction of donated  
322 prescription drugs under certain circumstances;  
323 providing recordkeeping requirements; requiring the  
324 department to establish, maintain, and publish a  
325 registry of participating repositories and available  
326 donated prescription drugs and supplies; requiring the  
327 department to publish certain information and forms on  
328 its website; providing immunity from civil and  
329 criminal liability and professional disciplinary  
330 action for program donors and participants under



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331 certain circumstances; providing specified immunity to  
332 pharmaceutical manufacturers under certain  
333 circumstances; requiring the department to adopt  
334 rules; amending s. 252.36, F.S.; authorizing the  
335 Governor to waive program patient eligibility  
336 requirements during a declared state of emergency;  
337 providing an effective date.