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LEGISLATIVE ACTION

Senate

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House

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.

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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.