

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; providing an effective date.

54
 55 Be It Enacted by the Legislature of the State of Florida:

56
 57 Section 1. Section 465.1902, Florida Statutes, is created
 58 to read:

59 465.1902 Prescription Drug Donation Repository Program.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

124 (4) REPOSITORIES.—

125 (a) A repository may accept and dispense eligible

126 donations to eligible patients under the program. The repository
127 must inspect, store, and dispense donations and report to the
128 department in accordance with this section.

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

131 1. A health care practitioner's office.

132 2. A pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

168 (c) Hospitals with closed drug delivery systems.

169 (d) Pharmacies.

170 (e) Drug manufacturers or wholesale distributors.

171 (f) Medical device manufacturers or suppliers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

205 (7) INSPECTION AND STORAGE.—

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

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

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

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

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

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

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

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

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

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

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

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

250 underinsured.

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

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

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

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

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

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

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

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

275 (9) RECALLED PRESCRIPTION DRUGS.—

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

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

284 (10) RECORDKEEPING.—

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

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

292 (11) REGISTRIES; PUBLICATION OF FORMS.—

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

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

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

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

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

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

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

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

324 252.36 Emergency management powers of the Governor.—

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

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

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