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Proposed Committee Substitute by the Committee on Appropriations
(Appropriations Subcommittee on Health and Human Services)

A bill to be entitled

An act relating to the Prescription Drug Donation Repository Program; creating s. 465.1902, F.S.; providing a short title; creating the Prescription Drug Donation Repository Program within the Department of Health; providing purpose; authorizing the department to contract with a third party to implement and administer the program; providing definitions; specifying entities that are eligible donors; providing criteria for eligible donations; prohibiting donations to specific patients; providing that certain prescription drugs eligible for return to stock must be credited to Medicaid under specified conditions and are not program eligible; prohibiting the donation of certain drugs pursuant to federal restrictions; authorizing repositories to refuse to accept donations of prescription drugs or supplies; providing inspection, inventory, and storage requirements for centralized and local repositories; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; requiring a local repository to notify the centralized repository within a specified timeframe after receiving a donation of prescription drugs or supplies; authorizing a centralized repository to redistribute prescription drugs or supplies; requiring local repositories to notify the department regarding participation in the



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28 program; providing conditions for dispensing donated
29 prescription drugs and supplies to eligible patients;
30 requiring repositories to establish a protocol for
31 notifying recipients of a prescription drug recall;
32 providing for destruction of donated prescription
33 drugs in the event of a drug recall; providing
34 recordkeeping requirements; requiring the department
35 to maintain and publish a registry of participating
36 local repositories and available donated prescription
37 drugs and supplies; specifying certain notice to
38 patients; providing immunity from civil and criminal
39 liability for participants under certain
40 circumstances; authorizing the department to establish
41 a direct-support organization to provide assistance
42 funding and promotional support for program
43 activities; specifying direct-support organization
44 purposes and objectives; prohibiting such direct-
45 support organization from lobbying and specifying that
46 such direct-support organization is not a lobbying
47 firm; specifying that the direct-support organization
48 must operate under contract with the department;
49 specifying required contract terms; providing for the
50 direct-support organization board of directors;
51 specifying the membership of such board; specifying
52 requirements relating to a direct-support
53 organization's use of department property; specifying
54 requirements for the deposit of funds by the direct-
55 support organization; providing for audits of a
56 direct-support organization; specifying a repeal,



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57 unless reviewed and saved from repeal by the
58 Legislature on a specified date; requiring the
59 department to adopt rules; amending s. 252.36, F.S.;
60 authorizing the Governor to waive the patient
61 eligibility requirements of s. 465.1902, F.S., during
62 a declared state of emergency; providing an effective
63 date.

64
65 Be It Enacted by the Legislature of the State of Florida:

66
67 Section 1. Section 465.1902, Florida Statutes, is created
68 to read:

69 465.1902 Prescription Drug Donation Repository Program.—

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

72 (2) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM.—The
73 Prescription Drug Donation Repository Program is created within
74 the Department of Health for the purpose of authorizing and
75 facilitating the donation of prescription drugs and supplies to
76 eligible patients. The department may contract with a third
77 party to implement and administer the program.

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

79 (a) “Centralized repository” means a distributor permitted
80 pursuant to chapter 499 which is approved by the department or
81 the contractor to accept, inspect, inventory, and distribute
82 donated drugs and supplies under this section.

83 (b) “Closed drug delivery system” means a system in which
84 the actual control of the unit-dose medication package is
85 maintained by the facility rather than by the individual



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86 patient.

87 (c) "Contractor" means the third-party vendor approved by
88 the department to implement and administer the program.

89 (d) "Controlled substance" means any substance listed under
90 Schedule II, Schedule III, Schedule IV, or Schedule V of s.
91 893.03.

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

93 (f) "Direct-support organization" means an entity that is
94 established pursuant to s. 20.058 and is:

95 1. A Florida corporation not for profit incorporated under
96 chapter 617, exempted from filing fees, and approved by the
97 Department of State.

98 2. Organized and operated to conduct programs and
99 activities; raise funds and request and receive grants, gifts,
100 and bequests of moneys; acquire, receive, hold, and invest, in
101 its own name, securities, funds, objects of value, or other
102 property, either real or personal; and make expenditures or
103 provide funding to or for the direct or indirect benefit of the
104 program.

105 (g) "Dispenser" means a dispensing health care practitioner
106 or pharmacist licensed to dispense medicinal drugs in the state.

107 (h) "Donor" means an entity that meets the requirements of
108 subsection (4).

109 (i) "Eligible patient" means a Florida resident who is
110 indigent, uninsured, or underinsured and has a valid
111 prescription for a prescription drug or supply that is eligible
112 for dispensing under the program.

113 (j) "Free clinic" means a clinic that delivers only medical
114 diagnostic services or nonsurgical medical treatment free of



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115 charge to all low-income recipients.

116 (k) "Health care practitioner" or "practitioner" means a
117 practitioner licensed under chapter 458, chapter 459, chapter
118 461, chapter 463, chapter 464, chapter 465, or chapter 466.

119 (l) "Indigent" means a person with an income that is below
120 200 percent of the federal poverty level as defined by the most
121 recently revised poverty income guidelines published by the
122 United States Department of Health and Human Services.

123 (m) "Local repository" means a health care practitioner's
124 office, a pharmacy, a hospital with a closed drug delivery
125 system, a nursing home facility with a closed drug delivery
126 system, a free clinic, or a nonprofit health clinic that is
127 licensed or permitted to dispense medicinal drugs in the state.

128 (n) "Nonprofit health clinic" means a nonprofit legal
129 entity that provides medical care to patients who are indigent,
130 uninsured, or underinsured, including, but not limited to, a
131 federally qualified health center as defined in 42 U.S.C. s.
132 1396d(1) (2) (B) and a rural health clinic as defined in 42 U.S.C.
133 s. 1396d(1) (1).

134 (o) "Nursing home facility" has the same meaning as in s.
135 400.021(12).

136 (p) "Prescriber" means a prescribing physician, prescribing
137 practitioner, or other health care practitioner authorized by
138 the laws of this state to prescribe medicinal drugs.

139 (q) "Prescription drug" has the same meaning as defined in
140 s. 465.003(8), but does not include controlled substances or
141 cancer drugs donated under s. 499.029.

142 (r) "Program" means the Prescription Drug Donation
143 Repository Program created by this section.



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144 (s) "Supplies" means any supply used in the administration
145 of a prescription drug.

146 (t) "Tamper-evident packaging" means a package that has one
147 or more indicators or barriers to entry which, if breached or
148 missing, can reasonably be expected to provide visible evidence
149 to consumers that tampering has occurred.

150 (u) "Underinsured" means a person who has third-party
151 insurance or is eligible to receive prescription drugs or
152 supplies through the Medicaid program or any other prescription
153 drug program funded in whole or in part by the Federal
154 Government, but has exhausted these benefits or does not have
155 prescription drug coverage for the drug prescribed.

156 (v) "Uninsured" means a person who has no third-party
157 insurance and is not eligible to receive prescription drugs or
158 supplies through the Medicaid program or any other prescription
159 drug program funded in whole or in part by the Federal
160 Government.

161 (4) DONOR ELIGIBILITY.—The program may only accept a
162 donation of a prescription drug or supply from:

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

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

167 (c) Hospitals with closed drug delivery systems.

168 (d) Pharmacies.

169 (e) Drug manufacturers or wholesale distributors.

170 (f) Medical device manufacturers or suppliers.

171 (g) Prescribers who receive prescription drugs or supplies
172 directly from a drug manufacturer, wholesale distributor, or



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173 pharmacy.

174 (5) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION.—

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

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

181 1. The drug is in its original sealed and tamper-evident
182 packaging. Single-unit-dose drugs may be accepted if the single-
183 unit-dose packaging is unopened.

184 2. The drug requires storage at normal room temperature per
185 the manufacturer or the United States Pharmacopeia.

186 3. The drug has been stored according to manufacturer or
187 United States Pharmacopeia storage requirements.

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

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

194 6. The packaging contains the lot number and expiration
195 date of the drug. If the lot number is not retrievable, all
196 specified medications must be destroyed in the event of a
197 recall.

198 7. The drug has an expiration date that is more than 3
199 months after the date that the drug was donated.

200 (c) The central repository or a local repository may only
201 accept supplies that are in their original, unopened, sealed



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202 packaging and have not been adulterated or misbranded.

203 (d) Prescription drugs and supplies may be donated on the
204 premises of the centralized repository or a local repository to
205 a person designated by the repository. A drop box may not be
206 used to accept donations.

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

209 (f) Prescription drugs billed to and paid for by Medicaid
210 in long-term care facilities which are eligible for return to
211 stock under federal Medicaid regulations must be credited to
212 Medicaid and are not eligible for donation under the program.

213 (g) Prescription drugs that are subject to a Federal Food
214 and Drug Administration Risk Evaluation and Mitigation Strategy
215 with Elements to Assure Safe Use are not eligible for donation
216 under the program.

217 (h) Nothing in this section requires the central repository
218 or a local repository to accept a donation of a prescription
219 drug or supplies.

220 (6) INSPECTION AND STORAGE.—

221 (a) A licensed pharmacist employed by or under contract
222 with the centralized repository or a local repository shall
223 inspect donated prescription drugs and supplies to determine
224 whether the donated prescription drugs or supplies:

- 225 1. Are eligible for donation under the program;
226 2. Have been adulterated or misbranded; and
227 3. Are safe and suitable for dispensing.

228 (b) The pharmacist who inspects the donated prescription
229 drugs or supplies shall sign an inspection record on a form
230 prescribed by the department and adopted in rule verifying that



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231 the criteria of paragraph (a) have been met and attach such
232 record to the copy of the inventory record. If a local
233 repository receives drugs and supplies from the centralized
234 repository, the local repository is not required to reinspect
235 the drugs and supplies.

236 (c) The centralized repository and local repositories shall
237 store donated prescription drugs and supplies in a secure
238 storage area under the environmental conditions specified by the
239 manufacturer or United States Pharmacopeia for the prescription
240 drugs or supplies being stored. Donated prescription drugs and
241 supplies may not be stored with nondonated inventory. A local
242 repository shall quarantine any donated prescription drugs or
243 supplies from all dispensing stock until the donated
244 prescription drugs or supplies are inspected and approved for
245 dispensing under the program.

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

250 (e) A local repository shall notify the centralized
251 repository within 5 days after receipt of any donation of
252 prescription drugs or supplies to the program. The notification
253 shall be on a form prescribed by the department and adopted by
254 rule.

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

257 (g) The centralized repository may redistribute
258 prescription drugs and supplies to facilitate dispensing to
259 either the centralized repository or to a local repository, as



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260 needed.

261 (7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.—

262 (a) A local repository must notify the department of its
263 intent to participate in the program before accepting or
264 dispensing any prescription drugs or supplies pursuant to this
265 section. The notification shall be on a form prescribed by the
266 department and adopted by rule and must, at a minimum, include:

267 1. The name, street address, website, and telephone number
268 of the local repository and any state-issued license or
269 registration number issued to the local repository, including
270 the name of the issuing agency.

271 2. The name and telephone number of the pharmacist employed
272 by or under contract with the local repository who is
273 responsible for the inspection of donated prescription drugs and
274 supplies.

275 3. A statement signed and dated by the responsible
276 pharmacist affirming that the local repository meets the
277 eligibility requirements of this section.

278 (b) A local repository may withdraw from participation in
279 the program at any time by providing written notice to the
280 department or contractor on a form prescribed by the department
281 and adopted by rule. The department shall adopt rules addressing
282 the disposition of any prescription drugs in the possession of
283 the local repository.

284 (8) DISPENSING.—

285 (a) Each eligible patient without a program identification
286 card must submit an intake collection form to a local repository
287 before receiving prescription drugs or supplies under the
288 program. The form shall be prescribed by the department and



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289 adopted by rule and, at a minimum, must include:

290 1. The name, street address, and telephone number of the
291 eligible patient.

292 2. The basis for eligibility, which must specify that the
293 patient is indigent, uninsured, or underinsured.

294 3. A statement signed and dated by the eligible patient
295 affirming that he or she meets the eligibility requirements of
296 this section.

297 (b) A local repository shall collect a signed and dated
298 intake collection form from each eligible patient receiving
299 prescription drugs or supplies under the program. The local
300 repository must issue a program identification card upon receipt
301 of a duly executed intake collection form. The program
302 identification card is valid for 1 year after issuance and must
303 be in a form prescribed by the department and adopted in rule.

304 (c) A local repository must send a summary of the intake
305 collection form data to the centralized pharmacy within 5 days
306 after receipt of a duly executed intake collection form.

307 (d) A dispenser may only dispense a donated prescription
308 drug or supplies, if available, to an eligible patient with a
309 program identification card or a duly executed intake collection
310 form.

311 (e) A dispenser shall inspect the donated prescription
312 drugs or supplies prior to dispensing such drugs or supplies.

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

315 (g) Donated prescription drugs and supplies may not be sold
316 or resold under this program.

317 (h) A dispenser of donated prescription drugs or supplies



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318 may not submit a claim or otherwise seek reimbursement from any
319 public or private third-party payor for donated prescription
320 drugs or supplies dispensed to any patient under this program.
321 However, a repository may charge a nominal handling fee,
322 established by department rule, for the preparation and
323 dispensing of prescription drugs or supplies under the program.

324 (i) A local repository that receives donated prescription
325 drugs or supplies may, with authorization from the centralized
326 repository, distribute the prescription drugs or supplies to
327 another local repository.

328 (9) RECALL AND DESTRUCTION OF PRESCRIPTION DRUGS AND
329 SUPPLIES.—

330 (a) The centralized repository and a local repository shall
331 be responsible for drug recalls and shall have an established
332 protocol to notify recipients in the event of a prescription
333 drug recall.

334 (b) Local repositories shall destroy all of the recalled or
335 expired prescription drugs or prescription drugs that are not
336 suitable for dispensing in the repository and complete a
337 destruction information form for all donated prescription drugs
338 destroyed, in accordance with rules adopted by the department.

339 (10) RECORDKEEPING.—

340 (a) Local repositories shall maintain records of
341 prescription drugs and supplies that were accepted, donated,
342 dispensed, distributed, or destroyed under the program.

343 (b) All records required to be maintained as a part of the
344 program shall be maintained in accordance with any applicable
345 practice acts. Local repositories shall submit these records
346 quarterly to the centralized repository for data collection, and



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347 the centralized repository shall submit these records and the
348 collected data in annual reports to the department.

349 (11) REGISTRIES AND FORMS.—

350 (a) The department shall establish and maintain registries
351 of all local repositories and available drugs and supplies under
352 the program. The registry of local repositories must include the
353 repository's name, address, website, and telephone number. The
354 registry of available drugs and supplies must include the name,
355 strength, available quantity, and expiration date of the drug or
356 supply and the name and contact information of the repositories
357 where such drug or supply is available. The department shall
358 publish the registries on its website.

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

361 (12) IMMUNITY.—

362 (a) Any donor of prescription drugs or supplies, or any
363 participant in the program, who exercises reasonable care in
364 donating, accepting, distributing, or dispensing prescription
365 drugs or supplies under the program, and the rules adopted
366 pursuant thereto, is immune from civil or criminal liability and
367 from professional disciplinary action of any kind for any
368 injury, death, or loss to person or property relating to such
369 activities.

370 (b) A pharmaceutical manufacturer who exercises reasonable
371 care is not liable for any claim or injury arising from the
372 transfer of any prescription drug under this section, including
373 but not limited to, liability for failure to transfer or
374 communicate product or consumer information regarding the
375 transferred drug, including the expiration date of the



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376 transferred drug.

377 (13) NOTICE TO PATIENTS.-Before dispensing a prescription
378 drug that has been donated under this program, the dispenser
379 must provide written notification to the patient, or to his or
380 her legal representative, receipt of which must be acknowledged
381 in writing, that:

382 (a) The prescription drug was donated to the program;

383 (b) The donors and participants in the program are granted
384 certain immunities as described in subsection (12); and

385 (c) The patient may not be required to pay for the
386 prescription drug, except for a nominal handling fee which may
387 not exceed the amount established by department rule.

388 (14) DIRECT-SUPPORT ORGANIZATION.-The department may
389 establish a direct-support organization to provide assistance,
390 funding, and promotional support for the activities authorized
391 for the program.

392 (a) Purposes and objectives.-The purposes and objectives of
393 the direct-support organization of the program must be
394 consistent with the goals of the department, in the best
395 interest of the state, and in accordance with the adopted goals
396 and mission of the department.

397 (b) Prohibition against lobbying.-The direct-support
398 organization is not considered a lobbying firm within the
399 meaning of s. 11.045. All expenditures of the direct-support
400 organization must be used for the program. No expenditures of
401 the direct-support organization may be used for the purpose of
402 lobbying as defined in s. 11.045.

403 (c) Contract.-The direct-support organization shall operate
404 under a written contract with the department. The contract must



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405 provide for a submission by the direct-support organization to
406 the department, by each August 1, and posting on the direct-
407 support organization's and department's websites, the following
408 information:

409 1. The articles of incorporation and bylaws of the direct-
410 support organization as approved by the department.

411 2. An annual budget for the approval of the department.

412 3. The code of ethics of the direct-support organization.

413 4. The statutory authority or executive order that created
414 the direct-support organization.

415 5. A brief description of the direct-support organization's
416 mission and any results obtained by the direct-support
417 organization.

418 6. A brief description of the direct-support organization's
419 plans for the next 3 fiscal years.

420 7. A copy of the direct-support organization's most recent
421 federal Internal Revenue Service Return Organization Exempt from
422 Income Tax form (Form 990).

423 8. Certification by the department that the direct-support
424 organization is complying with the terms of the contract and
425 operating in a manner consistent with the goals and purposes of
426 the department and the best interest of the program and the
427 state. Such certification must be made annually and reported in
428 the official minutes of a meeting of the direct-support
429 organization.

430 9. The reversion, without penalty, of moneys and property
431 held in trust by the direct-support organization for the benefit
432 of the program to the state if the department ceases to exist;
433 or reversion to the department if the direct-support



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434 organization is no longer approved to operate or ceases to
435 exist.

436 10. The fiscal year of the direct-support organization,
437 which must begin on July 1 of each year and end on June 30 of
438 the following year.

439 11. The disclosure of material provisions of the contract,
440 and the distinction between the department and the direct-
441 support organization, to donors of gifts, contributions, or
442 bequests, including such disclosure on all promotional and
443 fundraising publications.

444 12. All prescription drugs solicited by the direct-support
445 organization to be distributed to the centralized repository or
446 a local repository. The direct-support organization may not
447 possess any prescription drugs on behalf of the program.

448 (d) Board of directors.—The State Surgeon General shall
449 appoint a board of directors of the direct-support organization.
450 The board of directors shall consist of at least 5 members, but
451 not more than 15 members, who serve at the pleasure of the State
452 Surgeon General. The board members must elect a chair from among
453 its members. Board members must serve without compensation but
454 may be entitled to reimbursement of travel and per diem expenses
455 in accordance with s. 112.061, if funds are available for this
456 purpose.

457 (e) Use of property.—The department may allow, without
458 charge, appropriate use of fixed property, facilities, and
459 personnel services of the department by the direct-support
460 organization, subject to this subsection. For the purposes of
461 this paragraph, the term "personnel services" includes full-time
462 or part-time personnel, as well as payroll processing services.



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463 1. The department may prescribe any condition with which
464 the direct-support organization must comply in order to use
465 fixed property or facilities of the department.

466 2. The department may not permit the use of any fixed
467 property or facilities of the department by the direct-support
468 organization if it does not provide equal membership and
469 employment opportunities to all persons regardless of race,
470 color, religion, sex, age, or national origin.

471 3. The department shall adopt rules prescribing the
472 procedures by which the direct-support organization is governed
473 and any conditions with which a direct-support organization must
474 comply to use property or facilities of the department.

475 (f) Deposit of funds.—Any moneys may be held in a separate
476 depository account in the name of the direct-support
477 organization and subject to the provisions of the contract with
478 the department.

479 (g) Use of funds.—Funds designated for the direct-support
480 organization must be used for the enhancement of the projects of
481 the program and used in a manner consistent with that purpose.
482 Any administrative costs of running and promoting the purposes
483 of the corporation or program must be paid by private funds.

484 (h) Audit.—The direct-support organization shall provide
485 for an annual financial audit in accordance with s. 215.981.

486 (i) Repeal.—This subsection shall stand repealed on October
487 1, 2023, unless reviewed and saved from repeal by the
488 Legislature.

489 (15) RULEMAKING.—The department shall adopt rules necessary
490 to implement the requirements of this section. When applicable,
491 the rules may provide for the use of electronic forms,



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492 recordkeeping, and meeting by teleconference.

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

495 252.36 Emergency management powers of the Governor.—

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

498 (o) Waive the patient eligibility requirements of s.
499 465.1902.

500 Section 3. This act shall take effect July 1, 2018.