

By the Committees on Appropriations; and Health Policy; and
Senator Book

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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; creating the Prescription
5 Drug Donation Repository Program within the Department
6 of Health; providing a purpose for the program;
7 authorizing the department to contract with a third
8 party to implement and administer the program;
9 providing definitions; specifying entities that are
10 eligible donors; providing criteria for eligible
11 donations; prohibiting donations to specific patients;
12 providing that certain prescription drugs eligible for
13 return to stock must be credited to Medicaid under
14 specified conditions and are not program eligible;
15 prohibiting the donation of certain drugs pursuant to
16 federal restrictions; authorizing repositories to
17 refuse to accept donations of prescription drugs or
18 supplies; providing inspection, inventory, and storage
19 requirements for centralized and local repositories;
20 requiring inspection of donated prescription drugs and
21 supplies by a licensed pharmacist; requiring a local
22 repository to notify the centralized repository within
23 a specified timeframe after receiving a donation of
24 prescription drugs or supplies; authorizing a
25 centralized repository to redistribute prescription
26 drugs or supplies; requiring local repositories to
27 notify the department regarding participation in the
28 program; providing conditions for dispensing donated
29 prescription drugs and supplies to eligible patients;

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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 establish, maintain, and publish a registry of
36 participating local repositories and available donated
37 prescription drugs and supplies; providing immunity
38 from civil and criminal liability for participants
39 under certain circumstances; specifying certain notice
40 to patients; authorizing the department to establish a
41 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 and use of funds by the
55 direct-support organization; providing for annual
56 audits of a direct-support organization; providing for
57 future legislative review and repeal; requiring the
58 department to adopt rules; amending s. 252.36, F.S.;

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59 authorizing the Governor to waive the patient
60 eligibility requirements of s. 465.1902, F.S., during
61 a declared state of emergency; providing an effective
62 date.

63
64 Be It Enacted by the Legislature of the State of Florida:

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

68 465.1902 Prescription Drug Donation Repository Program.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

112 (j) "Free clinic" means a clinic that delivers only medical
113 diagnostic services or nonsurgical medical treatment free of
114 charge to all low-income recipients.

115 (k) "Health care practitioner" or "practitioner" means a
116 practitioner licensed under chapter 458, chapter 459, chapter

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117 461, chapter 463, chapter 464, chapter 465, or chapter 466.

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

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

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

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

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

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

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

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

145 (t) "Tamper-evident packaging" means a package that has one

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146 or more indicators or barriers to entry which, if breached or
147 missing, can reasonably be expected to provide visible evidence
148 to consumers that tampering has occurred.

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

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

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

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

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

166 (c) Hospitals with closed drug delivery systems.

167 (d) Pharmacies.

168 (e) Drug manufacturers or wholesale distributors.

169 (f) Medical device manufacturers or suppliers.

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

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

174 (a) All prescription drugs and supplies that have been

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175 approved for medical use in the United States and meet the
176 criteria for donation established by this section may be
177 accepted for donation under the program.

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

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

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

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

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

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

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

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

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

202 (d) Prescription drugs and supplies may be donated on the
203 premises of the centralized repository or a local repository to

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204 a person designated by the repository. A drop box may not be
205 used to accept donations.

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

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

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

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

219 (6) INSPECTION AND STORAGE.—

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

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

227 (b) The pharmacist who inspects the donated prescription
228 drugs or supplies shall sign an inspection record on a form
229 prescribed by the department and adopted in rule verifying that
230 the criteria of paragraph (a) have been met and attach such
231 record to the copy of the inventory record. If a local
232 repository receives drugs and supplies from the centralized

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233 repository, the local repository is not required to reinspect
234 the drugs and supplies.

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

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

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

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

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

260 (7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.—

261 (a) A local repository must notify the department of its

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

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

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

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

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

283 (8) DISPENSING.—

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

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

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

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

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

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

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

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

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

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

316 (h) A dispenser of donated prescription drugs or supplies
317 may not submit a claim or otherwise seek reimbursement from any
318 public or private third-party payor for donated prescription
319 drugs or supplies dispensed to any patient under this program.

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320 However, a repository may charge a nominal handling fee,
321 established by department rule, for the preparation and
322 dispensing of prescription drugs or supplies under the program.

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

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

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

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

338 (10) RECORDKEEPING.—

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

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

348 (11) REGISTRIES AND FORMS.—

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

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

360 (12) IMMUNITY.—

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

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

376 (13) NOTICE TO PATIENTS.—Before dispensing a prescription
377 drug that has been donated under this program, the dispenser

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378 must provide written notification to the patient, or to his or
379 her legal representative, receipt of which must be acknowledged
380 in writing, that:

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

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

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

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

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

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

402 (c) Contract.-The direct-support organization shall operate
403 under a written contract with the department. The contract must
404 provide for a submission by the direct-support organization to
405 the department, by each August 1, and posting on the direct-
406 support organization's and department's websites, the following

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407 information:408 1. The articles of incorporation and bylaws of the direct-
409 support organization as approved by the department.410 2. An annual budget for the approval of the department.411 3. The code of ethics of the direct-support organization.412 4. The statutory authority or executive order that created
413 the direct-support organization.414 5. A brief description of the direct-support organization's
415 mission and any results obtained by the direct-support
416 organization.417 6. A brief description of the direct-support organization's
418 plans for the next 3 fiscal years.419 7. A copy of the direct-support organization's most recent
420 federal Internal Revenue Service Return Organization Exempt from
421 Income Tax form (Form 990).422 8. Certification by the department that the direct-support
423 organization is complying with the terms of the contract and
424 operating in a manner consistent with the goals and purposes of
425 the department and the best interest of the program and the
426 state. Such certification must be made annually and reported in
427 the official minutes of a meeting of the direct-support
428 organization.429 9. The reversion, without penalty, of moneys and property
430 held in trust by the direct-support organization for the benefit
431 of the program to the state if the department ceases to exist;
432 or reversion to the department if the direct-support
433 organization is no longer approved to operate or ceases to
434 exist.435 10. The fiscal year of the direct-support organization,

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436 which must begin on July 1 of each year and end on June 30 of
437 the following year.

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

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

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

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

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

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

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

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

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

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

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

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

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

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494 252.36 Emergency management powers of the Governor.—
495 (5) In addition to any other powers conferred upon the
496 Governor by law, she or he may:
497 (o) Waive the patient eligibility requirements of s.
498 465.1902.
499 Section 3. This act shall take effect July 1, 2018.