

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; authorizing the department to contract  
8           with a third-party vendor to administer the program;  
9           specifying entities that are eligible donors;  
10          providing criteria and procedures 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 and may  
14          not be donated under the program; prohibiting the  
15          donation of certain drugs pursuant to federal  
16          restrictions; clarifying that a repository is not  
17          required 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 the  
25          centralized repository to redistribute prescription

26 | drugs or supplies; authorizing a local repository to  
27 | transfer prescription drugs or supplies to another  
28 | local repository with authorization from the  
29 | centralized repository; requiring a local repository  
30 | to notify the department of its intent to participate  
31 | in the program; providing notification requirements;  
32 | providing a procedure for a local repository to  
33 | withdraw from participation in the program; requiring  
34 | the department to adopt rules regarding the  
35 | disposition of prescription drugs and supplies of a  
36 | withdrawing local repository; specifying conditions  
37 | for dispensing donated prescription drugs and supplies  
38 | to eligible patients; providing intake collection form  
39 | requirements; requiring a local repository to issue an  
40 | eligible patient who completes an intake collection  
41 | form a program identification card; prohibiting the  
42 | sale of donated prescription drugs and supplies under  
43 | the program; requiring repositories to establish a  
44 | protocol for notifying recipients of a prescription  
45 | drug recall; providing for destruction of donated  
46 | prescription drugs under certain circumstances;  
47 | providing recordkeeping requirements; requiring the  
48 | centralized repository to submit an annual report to  
49 | the department; requiring the department or contractor  
50 | to establish, maintain, and publish a registry of

51 participating local repositories and available donated  
52 prescription drugs and supplies; requiring the  
53 department to publish certain information and forms on  
54 its website; providing immunity from civil and  
55 criminal liability and from professional disciplinary  
56 action for participants under certain circumstances;  
57 providing immunity to pharmaceutical manufacturers,  
58 under certain circumstances, from any claim or injury  
59 arising from the donation of any prescription drug or  
60 supply under the program; requiring dispensers to  
61 provide certain notice to patients; authorizing the  
62 department to establish a direct-support organization  
63 to provide assistance, funding, and promotional  
64 support for program activities; providing  
65 organizational requirements for a direct-support  
66 organization; specifying direct-support organization  
67 purposes and objectives; prohibiting the direct-  
68 support organization from lobbying; specifying that  
69 the direct-support organization is not a lobbying  
70 firm; prohibiting the direct-support organization from  
71 possessing prescription drugs on behalf of the  
72 program; providing limitations on expenditures of such  
73 direct-support organization; specifying that the  
74 direct-support organization must operate under  
75 contract with the department; specifying required

76 contract terms; providing for the direct-support  
 77 organization board of directors; specifying the  
 78 board's membership requirements; specifying  
 79 requirements and requiring the department to adopt  
 80 rules relating to a direct-support organization's use  
 81 of department property; specifying requirements for  
 82 the deposit and use of funds by the direct-support  
 83 organization; providing for annual audits of a direct-  
 84 support organization; providing for future legislative  
 85 review and repeal of provisions relating to the  
 86 direct-support organization; requiring the department  
 87 to adopt rules; amending s. 252.36, F.S.; authorizing  
 88 the Governor to waive program patient eligibility  
 89 requirements during a declared state of emergency;  
 90 authorizing positions and providing appropriations;  
 91 providing an effective date.

92  
 93 Be It Enacted by the Legislature of the State of Florida:

94  
 95 Section 1. Section 465.1902, Florida Statutes, is created  
 96 to read:

97 465.1902 Prescription Drug Donation Repository Program.—

98 (1) SHORT TITLE.—This section may be cited as the

99 "Prescription Drug Donation Repository Program Act."

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

101 (a) "Centralized repository" means a distributor permitted  
102 under chapter 499 who is approved by the department or the  
103 contractor to accept, inspect, inventory, and distribute donated  
104 drugs and supplies under this section.

105 (b) "Closed drug delivery system" means a system in which  
106 the actual control of the unit-dose medication package is  
107 maintained by the facility, rather than by the individual  
108 patient.

109 (c) "Contractor" means the third-party vendor approved by  
110 the department to implement and administer the program as  
111 authorized in subsection (4).

112 (d) "Controlled substance" means any substance listed  
113 under Schedule II, Schedule III, Schedule IV, or Schedule V of  
114 s. 893.03.

115 (e) "Direct-support organization" means the entity created  
116 under subsection (15).

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

120 (g) "Donor" means an entity specified in subsection (5).

121 (h) "Eligible patient" means a Florida resident who is  
122 indigent, uninsured, or underinsured and who has a valid  
123 prescription for a prescription drug or supply that may be  
124 dispensed under the program.

125 (i) "Free clinic" means a clinic that delivers only

126 medical diagnostic services or nonsurgical medical treatment  
 127 free of charge to low-income recipients.

128 (j) "Health care practitioner" or "practitioner" means a  
 129 practitioner licensed under this chapter, chapter 458, chapter  
 130 459, chapter 461, chapter 463, chapter 464, or chapter 466.

131 (k) "Indigent" means an individual whose family income for  
 132 the 12 months preceding the determination of income is below 200  
 133 percent of the federal poverty level as defined by the most  
 134 recently revised poverty income guidelines published by the  
 135 United States Department of Health and Human Services.

136 (l) "Local repository" means a health care practitioner's  
 137 office, a pharmacy, a hospital with a closed drug delivery  
 138 system, a nursing home facility with a closed drug delivery  
 139 system, or a free clinic or nonprofit health clinic that is  
 140 licensed or permitted to dispense medicinal drugs in the state.

141 (m) "Nonprofit health clinic" means a nonprofit legal  
 142 entity that provides medical care to patients who are indigent,  
 143 uninsured, or underinsured. The term includes, but is not  
 144 limited to, a federally qualified health center as defined in 42  
 145 U.S.C. s. 1396d(1) (2) (B) and a rural health clinic as defined in  
 146 42 U.S.C. s. 1396d(1) (1).

147 (n) "Nursing home facility" has the same meaning as in s.  
 148 400.021.

149 (o) "Prescriber" means a health care practitioner who,  
 150 within the scope of his or her practice act, is authorized to

151 prescribe medicinal drugs.

152 (p) "Prescription drug" has the same meaning as the term  
153 "medicinal drugs" or "drugs," as those terms are defined in s.  
154 465.003(8), but does not include controlled substances or cancer  
155 drugs donated under s. 499.029.

156 (q) "Program" means the Prescription Drug Donation  
157 Repository Program created by this section.

158 (r) "Supplies" means any supply used in the administration  
159 of a prescription drug.

160 (s) "Tamper-evident packaging" means a package that has  
161 one or more indicators or barriers to entry which, if breached  
162 or missing, can reasonably be expected to provide visible  
163 evidence to consumers that tampering has occurred.

164 (t) "Underinsured" means a person who has third-party  
165 insurance or is eligible to receive prescription drugs or  
166 supplies through the Medicaid program or any other prescription  
167 drug program funded in whole or in part by the Federal  
168 Government, but who has exhausted these benefits or does not  
169 have prescription drug coverage for the drug prescribed.

170 (u) "Uninsured" means a person who has no third-party  
171 insurance and is not eligible to receive prescription drugs or  
172 supplies through the Medicaid program or any other prescription  
173 drug program funded in whole or in part by the Federal  
174 Government.

175 (3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM;

176 CREATION; PURPOSE.—The Prescription Drug Donation Repository  
 177 Program is created within the department for the purpose of  
 178 authorizing and facilitating the donation of prescription drugs  
 179 and supplies to eligible patients.

180 (4) PROGRAM IMPLEMENTATION; ADMINISTRATION.—The department  
 181 may contract with a third-party vendor to administer the  
 182 program.

183 (5) DONOR ELIGIBILITY.—The centralized repository or a  
 184 local repository may accept a donation of a prescription drug or  
 185 supply only from:

186 (a) Nursing home facilities with closed drug delivery  
 187 systems.

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

190 (c) Hospitals with closed drug delivery systems.

191 (d) Pharmacies.

192 (e) Drug manufacturers or wholesale distributors.

193 (f) Medical device manufacturers or suppliers.

194 (g) Prescribers who receive prescription drugs or supplies  
 195 directly from a drug manufacturer, wholesale distributor, or  
 196 pharmacy.

197 (6) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION;  
 198 DONATION REQUIREMENTS; PROHIBITED DONATIONS.—

199 (a) Only prescription drugs and supplies that have been  
 200 approved for medical use in the United States and that meet the

201 criteria for donation established by this section may be  
202 accepted for donation under the program. Donations must be made  
203 on the premises of the centralized repository or a local  
204 repository to a person designated by the repository. A drop box  
205 may not be used to accept donations.

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

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

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

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

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

218 5. The packaging does not have any physical signs of  
219 tampering, misbranding, deterioration, compromised integrity, or  
220 adulteration.

221 6. The packaging indicates the lot number and expiration  
222 date of the drug. If the lot number is not retrievable, all  
223 specified medications must be destroyed in the event of a  
224 recall.

225 7. The drug has an expiration date that is more than 3

226 months after the date that the drug was donated.

227 (c) The centralized repository or a local repository may  
228 accept supplies only if they are in their original, unopened,  
229 sealed packaging and have not been tampered with or misbranded.

230 (d) Prescription drugs or supplies may not be donated to a  
231 specific patient.

232 (e) Prescription drugs billed to and paid for by Medicaid  
233 in long-term care facilities which are eligible for return to  
234 stock under federal Medicaid regulations must be credited to  
235 Medicaid and may not be donated under the program.

236 (f) Prescription drugs with an approved Federal Food and  
237 Drug Administration Risk Evaluation and Mitigation Strategy that  
238 includes Elements to Assure Safe Use are not eligible for  
239 donation under the program.

240 (g) This section does not require the centralized  
241 repository or a local repository to accept a donation of  
242 prescription drugs or supplies.

243 (7) INSPECTION AND STORAGE.—

244 (a) A licensed pharmacist employed by or under contract  
245 with the centralized repository or a local repository shall  
246 inspect donated prescription drugs and supplies to determine  
247 whether they meet the requirements of subsections (5) and (6).

248 (b) The inspecting pharmacist must sign an inspection  
249 record on a form prescribed by the department by rule which  
250 verifies that the prescription drugs and supplies meet the

251 criteria of subsections (5) and (6) and must attach the record  
252 to the inventory required by paragraph (d). A local repository  
253 that receives drugs and supplies from the centralized repository  
254 is not required to reinspect them.

255 (c) The centralized repository and local repositories  
256 shall store donated prescription drugs and supplies in a secure  
257 storage area under the environmental conditions specified by the  
258 manufacturer or the United States Pharmacopeia for the  
259 respective prescription drugs or supplies. Donated prescription  
260 drugs and supplies may not be stored with other inventory. A  
261 local repository shall quarantine donated prescription drugs or  
262 supplies until they are inspected and approved for dispensing  
263 under this section.

264 (d) The centralized repository and local repositories  
265 shall maintain an inventory of all donated prescription drugs or  
266 supplies. Such inventory at local repositories shall be recorded  
267 on a form prescribed by the department by rule.

268 (e) A local repository shall notify the centralized  
269 repository within 5 days after receipt of any donation of  
270 prescription drugs or supplies to the program. The notification  
271 must be on a form prescribed by the department by rule.

272 (f) The centralized repository may redistribute  
273 prescription drugs and supplies by transferring them to or from  
274 the centralized repository and a local repository, as needed. A  
275 local repository that receives donated prescription drugs or

276 supplies may, with authorization from the centralized  
277 repository, distribute the prescription drugs or supplies to  
278 another local repository.

279 (8) PROGRAM PARTICIPATION.—

280 (a) A practitioner, pharmacy, facility, or clinic must  
281 notify the department of its intent to participate in the  
282 program as a local repository before accepting or dispensing any  
283 prescription drugs or supplies pursuant to this section. The  
284 notification must be made on a form prescribed by the department  
285 by rule and must, at a minimum, include:

286 1. The name, street address, website, and telephone number  
287 of the intended local repository and any license or registration  
288 number issued by the state to the intended local repository,  
289 including the name of the issuing agency.

290 2. The name and telephone number of the pharmacist  
291 employed by or under contract with the intended local repository  
292 who is responsible for the inspection of donated prescription  
293 drugs and supplies.

294 3. A signed and dated statement by the responsible  
295 pharmacist affirming that the intended local repository meets  
296 the eligibility requirements of this section.

297 (b) A local repository may withdraw from participation in  
298 the program at any time by providing written notice to the  
299 department or contractor, as appropriate, on a form prescribed  
300 by the department by rule. The department shall adopt rules

301 addressing the disposition of prescription drugs and supplies in  
 302 the possession of the withdrawing local repository.

303 (9) DISPENSING REQUIREMENTS; PROHIBITIONS.—

304 (a) Each eligible patient without a program identification  
 305 card must submit an intake collection form to a local repository  
 306 before receiving prescription drugs or supplies under the  
 307 program. The department shall prescribe a form by rule, which  
 308 must include at least all of the following:

309 1. The name, street address, and telephone number of the  
 310 eligible patient.

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

313 3. A statement signed and dated by the eligible patient  
 314 affirming that he or she meets the eligibility requirements of  
 315 this section.

316 (b) Upon receipt of a completed and signed intake  
 317 collection form, the local repository shall issue him or her a  
 318 program identification card, which is valid for 1 year after its  
 319 date of issuance. The card must be in a form prescribed by the  
 320 department by rule.

321 (c) The local repository shall send a summary of each  
 322 intake collection form to the centralized pharmacy within 5 days  
 323 after receiving it.

324 (d) A dispenser may dispense donated prescription drugs or  
 325 supplies only to an eligible patient who has a program

326 identification card or who has submitted a completed intake  
327 collection form.

328 (e) A dispenser shall inspect the donated prescription  
329 drugs or supplies before dispensing them.

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

332 (g) Donated prescription drugs and supplies may not be  
333 sold or resold under the program.

334 (h) A dispenser of donated prescription drugs or supplies  
335 may not submit a claim or otherwise seek reimbursement from any  
336 public or private third-party payor for donated prescription  
337 drugs or supplies dispensed under this program.

338 (10) RECALLED PRESCRIPTION DRUGS AND SUPPLIES.—

339 (a) The centralized repository and each local repository  
340 shall establish and follow a protocol for notifying recipients  
341 in the event of a prescription drug recall.

342 (b) Local repositories shall destroy all recalled or  
343 expired prescription drugs and all prescription drugs that are  
344 not suitable for dispensing in the repository. Local  
345 repositories must complete a destruction information form for  
346 all such drugs, in accordance with department rule.

347 (11) RECORDKEEPING.—

348 (a) Local repositories shall maintain records of  
349 prescription drugs and supplies that are accepted, donated,  
350 dispensed, distributed, or destroyed under the program.

351 (b) All required records must be maintained in accordance  
352 with any applicable practice act. Local repositories shall  
353 submit these records quarterly to the centralized repository for  
354 data collection, and the centralized repository shall submit  
355 these records and the collected data in annual reports to the  
356 department.

357 (12) REGISTRIES; PUBLICATION OF FORMS.—

358 (a) The department or contractor shall establish and  
359 maintain registries of all local repositories and of  
360 prescription drugs and supplies available under the program. The  
361 registry of local repositories must include each repository's  
362 name, address, website, and telephone number. The registry of  
363 available prescription drugs and supplies must include the name,  
364 strength, available quantity, and expiration date of the  
365 prescription drug or supplies and the name and contact  
366 information of each repository where such drug or supplies are  
367 available. The department shall publish the registries on its  
368 website.

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

371 (13) IMMUNITY FROM LIABILITY, DISCIPLINARY ACTION.—

372 (a) Any donor of prescription drugs or supplies and any  
373 participant in the program who exercises reasonable care in  
374 donating, accepting, distributing, or dispensing prescription  
375 drugs or supplies under the program is immune from civil or

376 criminal liability and from professional disciplinary action by  
377 the state for any injury, death, or loss to person or property  
378 relating to such activities.

379 (b) A pharmaceutical manufacturer who exercises reasonable  
380 care is not liable for any claim or injury arising from the  
381 donation of any prescription drug or supply under this section,  
382 including, but not limited to, liability for failure to transfer  
383 or communicate product or consumer information regarding the  
384 donated prescription drug, including its expiration date.

385 (14) NOTICE TO PATIENTS.—Before dispensing a donated  
386 prescription drug under the program, the dispenser must provide  
387 written notification to the eligible patient or his or her legal  
388 representative, receipt of which must be acknowledged in  
389 writing, of all of the following information:

390 (a) The prescription drug was donated to the program.

391 (b) The donors and participants in the program are immune  
392 from civil or criminal liability or disciplinary action.

393 (c) The eligible patient is not required to pay for the  
394 prescription drug.

395 (15) DIRECT-SUPPORT ORGANIZATION.—The department may  
396 establish a direct-support organization to provide assistance,  
397 funding, and promotional support for the activities authorized  
398 under the act.

399 (a) Entity organization.—The direct-support organization  
400 must operate in accordance with s. 20.058 and is:

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

404 2. Organized and operated to conduct programs and  
405 activities; raise funds and request and receive grants, gifts,  
406 and bequests of moneys; acquire, receive, hold, and invest, in  
407 its own name, securities, funds, objects of value, or other  
408 property, either real or personal; and make expenditures or  
409 provide funding to or for the direct or indirect benefit of the  
410 program.

411 (b) Purposes and objectives.—The purposes and objectives  
412 of the direct-support organization must be consistent with the  
413 goals of the department, in the best interest of the state, and  
414 in accordance with the adopted goals and the mission of the  
415 department.

416 (c) Prohibition against lobbying.—The direct-support  
417 organization is not considered a lobbying firm, as that term is  
418 defined in s. 11.045(1). All expenditures of the direct-support  
419 organization must be directly related to program administration  
420 within the requirements of this section. Funds of the direct-  
421 support organization may not be used for the purpose of  
422 lobbying, as that term is defined in s. 11.045(1).

423 (d) Possession of prescription drugs.—The direct-support  
424 organization may not possess any prescription drugs on behalf of  
425 the program.

426        (e) Contract.—The direct-support organization shall  
427 operate under a written contract with the department.

428        1. The contract must require the direct-support  
429 organization to submit to the department, annually by August 1,  
430 the following information, which must be posted on the websites  
431 of the direct-support organization and the department:

432            a. The articles of incorporation and bylaws of the direct-  
433 support organization, as approved by the department.

434            b. A proposed annual budget for the approval of the  
435 department.

436            c. The code of ethics of the direct-support organization.

437            d. The statutory authority or executive order that created  
438 the direct-support organization.

439            e. A brief description of the direct-support  
440 organization's mission and any results obtained by the direct-  
441 support organization.

442            f. A brief description of the direct-support  
443 organization's annual plan for each of the next 3 fiscal years.

444            g. A copy of the direct-support organization's most recent  
445 federal Internal Revenue Service Return Organization Exempt from  
446 Income Tax form (Form 990).

447            h. Certification by the department that the direct-support  
448 organization is complying with the terms of the contract and  
449 operating in a manner consistent with the goals and purposes of  
450 the department and the best interest of the program and the

451 state. Such certification must be made annually and reported in  
452 the official minutes of a meeting of the board of directors of  
453 the direct-support organization.

454 2. The contract must, at a minimum, provide for:

455 a. The reversion without penalty to the department, or to  
456 the state if the department ceases to exist, of all moneys and  
457 property held in trust by the direct-support organization for  
458 the benefit of the program if the direct-support organization  
459 ceases to exist or if the contract is terminated.

460 b. A disclosure of material provisions of the contract and  
461 the distinction between the department and the direct-support  
462 organization to appear on all promotional and fundraising  
463 publications.

464 c. A list of prescription drugs solicited by the direct-  
465 support organization for distribution to the centralized  
466 repository or a local repository.

467 (f) Board of directors.—The State Surgeon General shall  
468 appoint the board of directors, which must consist of at least 5  
469 members, but not more than 15 members, who serve at his or her  
470 pleasure. The board must elect a chair from among its members.  
471 Board members must serve without compensation but may be  
472 entitled to reimbursement of travel and per diem expenses in  
473 accordance with s. 112.061, if funds are available for this  
474 purpose.

475 (g) Use of property.—The department may allow, without

476 charge, appropriate use of fixed property, facilities, and  
477 personnel services of the department by the direct-support  
478 organization for purposes related to the program. For purposes  
479 of this paragraph, the term "personnel services" includes full-  
480 time or part-time personnel, as well as payroll processing  
481 services.

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

485 2. The department may not allow the use of any fixed  
486 property or facilities of the department by the direct-support  
487 organization if the organization does not provide equal  
488 membership and employment opportunities to all persons  
489 regardless of race, color, religion, sex, age, or national  
490 origin.

491 3. The department shall adopt rules prescribing the  
492 procedures by which the direct-support organization is governed  
493 and any conditions with which a direct-support organization must  
494 comply to use property or facilities of the department.

495 (h) *Deposit of funds.*—Any moneys of the direct-support  
496 organization may be held in a separate depository account in the  
497 name of the organization and subject to the provisions of the  
498 organization's contract with the department.

499 (i) *Use of funds.*—Funds designated for the direct-support  
500 organization must be used for the enhancement of program

501 projects and in a manner consistent with that purpose. Any  
 502 administrative costs of running and promoting the purposes of  
 503 the organization or program must be paid by private funds.

504 (j) Audit.—The direct-support organization shall provide  
 505 for an annual financial audit in accordance with s. 215.981.

506 (k) Repeal.—This subsection is repealed on October 1,  
 507 2024, unless reviewed and saved from repeal by the Legislature.

508 (16) RULEMAKING.—The department shall adopt rules  
 509 necessary to administer this section. When applicable, the rules  
 510 may provide for the use of electronic forms, recordkeeping, and  
 511 meeting by teleconference.

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

514 252.36 Emergency management powers of the Governor.—

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

517 (o) Waive the patient eligibility requirements of s.  
 518 465.1902.

519 Section 3. For the 2019-2020 fiscal year, two full-time  
 520 equivalent positions with associated salary rate of 150,449 are  
 521 authorized and the sums of \$325,423 in recurring funds and  
 522 \$78,233 in nonrecurring funds from the Grants and Donations  
 523 Trust Fund are appropriated to the Department of Health for the  
 524 purpose of implementing the requirements of this act.

525 Section 4. This act shall take effect July 1, 2019.