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LEGISLATIVE ACTION

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| Senate | . | House |
| Comm: RCS | . | |
| 02/14/2018 | . | |
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Appropriations Subcommittee on Health and Human Services (Book)
recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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

465.1902 Prescription Drug Donation Repository Program.—

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

“Prescription Drug Donation Repository Program Act.”



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11 (2) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM.—The
12 Prescription Drug Donation Repository Program is created within
13 the Department of Health for the purpose of authorizing and
14 facilitating the donation of prescription drugs and supplies to
15 eligible patients. The department may contract with a third
16 party to implement and administer the program.

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

18 (a) "Centralized repository" means a distributor permitted
19 pursuant to chapter 499 which is approved by the department or
20 the contractor to accept, inspect, inventory, and distribute
21 donated drugs and supplies under this section.

22 (b) "Closed drug delivery system" means a system in which
23 the actual control of the unit-dose medication package is
24 maintained by the facility rather than by the individual
25 patient.

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

28 (d) "Controlled substance" means any substance listed under
29 Schedule II, Schedule III, Schedule IV, or Schedule V of s.
30 893.03.

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

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

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

37 2. Organized and operated to conduct programs and
38 activities; raise funds and request and receive grants, gifts,
39 and bequests of moneys; acquire, receive, hold, and invest, in



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40 its own name, securities, funds, objects of value, or other
41 property, either real or personal; and make expenditures or
42 provide funding to or for the direct or indirect benefit of the
43 program.

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

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

48 (i) "Eligible patient" means a Florida resident who is
49 indigent, uninsured, or underinsured and has a valid
50 prescription for a prescription drug or supply that is eligible
51 for dispensing under the program.

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

55 (k) "Health care practitioner" or "practitioner" means a
56 practitioner licensed under chapter 458, chapter 459, chapter
57 461, chapter 463, chapter 464, chapter 465, or chapter 466.

58 (l) "Indigent" means a person with an income that is below
59 200 percent of the federal poverty level as defined by the most
60 recently revised poverty income guidelines published by the
61 United States Department of Health and Human Services.

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

67 (n) "Nonprofit health clinic" means a nonprofit legal
68 entity that provides medical care to patients who are indigent,



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69 uninsured, or underinsured, including, but not limited to, a
70 federally qualified health center as defined in 42 U.S.C. s.
71 1396d(1)(2)(B) and a rural health clinic as defined in 42 U.S.C.
72 s. 1396d(1)(1).

73 (o) "Nursing home facility" has the same meaning as in s.
74 400.021(12).

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

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

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

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

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

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

95 (v) "Uninsured" means a person who has no third-party
96 insurance and is not eligible to receive prescription drugs or
97 supplies through the Medicaid program or any other prescription



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98 drug program funded in whole or in part by the Federal
99 Government.

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

102 (a) Nursing home facilities with closed drug delivery
103 systems.

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

106 (c) Hospitals with closed drug delivery systems.

107 (d) Pharmacies.

108 (e) Drug manufacturers or wholesale distributors.

109 (f) Medical device manufacturers or suppliers.

110 (g) Prescribers who receive prescription drugs or supplies
111 directly from a drug manufacturer, wholesale distributor, or
112 pharmacy.

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

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

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

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

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

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



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

130 5. The packaging does not have any physical signs of
131 tampering, misbranding, deterioration, compromised integrity, or
132 adulteration.

133 6. The packaging contains the lot number and expiration
134 date of the drug. If the lot number is not retrievable, all
135 specified medications must be destroyed in the event of a
136 recall.

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

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

142 (d) Prescription drugs and supplies may be donated on the
143 premises of the centralized repository or a local repository to
144 a person designated by the repository. A drop box may not be
145 used to accept donations.

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

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

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



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156 (h) Nothing in this section requires the central repository
157 or a local repository to accept a donation of a prescription
158 drug or supplies.

159 (6) INSPECTION AND STORAGE.-

160 (a) A licensed pharmacist employed by or under contract
161 with the centralized repository or a local repository shall
162 inspect donated prescription drugs and supplies to determine
163 whether the donated prescription drugs or supplies:

- 164 1. Are eligible for donation under the program;
165 2. Have been adulterated or misbranded; and
166 3. Are safe and suitable for dispensing.

167 (b) The pharmacist who inspects the donated prescription
168 drugs or supplies shall sign an inspection record on a form
169 prescribed by the department and adopted in rule verifying that
170 the criteria of paragraph (a) have been met and attach such
171 record to the copy of the inventory record. If a local
172 repository receives drugs and supplies from the centralized
173 repository, the local repository is not required to reinspect
174 the drugs and supplies.

175 (c) The centralized repository and local repositories shall
176 store donated prescription drugs and supplies in a secure
177 storage area under the environmental conditions specified by the
178 manufacturer or United States Pharmacopeia for the prescription
179 drugs or supplies being stored. Donated prescription drugs and
180 supplies may not be stored with nondonated inventory. A local
181 repository shall quarantine any donated prescription drugs or
182 supplies from all dispensing stock until the donated
183 prescription drugs or supplies are inspected and approved for
184 dispensing under the program.



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

189 (e) A local repository shall notify the centralized
190 repository within 5 days after receipt of any donation of
191 prescription drugs or supplies to the program. The notification
192 shall be on a form prescribed by the department and adopted by
193 rule.

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

196 (g) The centralized repository may redistribute
197 prescription drugs and supplies to facilitate dispensing to
198 either the centralized repository or to a local repository, as
199 needed.

200 (7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.—

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

206 1. The name, street address, website, and telephone number
207 of the local repository and any state-issued license or
208 registration number issued to the local repository, including
209 the name of the issuing agency.

210 2. The name and telephone number of the pharmacist employed
211 by or under contract with the local repository who is
212 responsible for the inspection of donated prescription drugs and
213 supplies.



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214 3. A statement signed and dated by the responsible
215 pharmacist affirming that the local repository meets the
216 eligibility requirements of this section.

217 (b) A local repository may withdraw from participation in
218 the program at any time by providing written notice to the
219 department or contractor on a form prescribed by the department
220 and adopted by rule. The department shall adopt rules addressing
221 the disposition of any prescription drugs in the possession of
222 the local repository.

223 (8) DISPENSING.—

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

229 1. The name, street address, and telephone number of the
230 eligible patient.

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

233 3. A statement signed and dated by the eligible patient
234 affirming that he or she meets the eligibility requirements of
235 this section.

236 (b) A local repository shall collect a signed and dated
237 intake collection form from each eligible patient receiving
238 prescription drugs or supplies under the program. The local
239 repository must issue a program identification card upon receipt
240 of a duly executed intake collection form. The program
241 identification card is valid for 1 year after issuance and must
242 be in a form prescribed by the department and adopted in rule.



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

246 (d) A dispenser may only dispense a donated prescription
247 drug or supplies, if available, to an eligible patient with a
248 program identification card or a duly executed intake collection
249 form.

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

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

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

256 (h) A dispenser of donated prescription drugs or supplies
257 may not submit a claim or otherwise seek reimbursement from any
258 public or private third-party payor for donated prescription
259 drugs or supplies dispensed to any patient under this program.
260 However, a repository may charge a nominal handling fee,
261 established by department rule, for the preparation and
262 dispensing of prescription drugs or supplies under the program.

263 (i) A local repository that receives donated prescription
264 drugs or supplies may, with authorization from the centralized
265 repository, distribute the prescription drugs or supplies to
266 another local repository.

267 (9) RECALL AND DESTRUCTION OF PRESCRIPTION DRUGS AND
268 SUPPLIES.—

269 (a) The centralized repository and a local repository shall
270 be responsible for drug recalls and shall have an established
271 protocol to notify recipients in the event of a prescription



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272 drug recall.

273 (b) Local repositories shall destroy all of the recalled or
274 expired prescription drugs or prescription drugs that are not
275 suitable for dispensing in the repository and complete a
276 destruction information form for all donated prescription drugs
277 destroyed, in accordance with rules adopted by the department.

278 (10) RECORDKEEPING.—

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

282 (b) All records required to be maintained as a part of the
283 program shall be maintained in accordance with any applicable
284 practice acts. Local repositories shall submit these records
285 quarterly to the centralized repository for data collection, and
286 the centralized repository shall submit these records and the
287 collected data in annual reports to the department.

288 (11) REGISTRIES AND FORMS.—

289 (a) The department shall establish and maintain registries
290 of all local repositories and available drugs and supplies under
291 the program. The registry of local repositories must include the
292 repository's name, address, website, and telephone number. The
293 registry of available drugs and supplies must include the name,
294 strength, available quantity, and expiration date of the drug or
295 supply and the name and contact information of the repositories
296 where such drug or supply is available. The department shall
297 publish the registries on its website.

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

300 (12) IMMUNITY.—



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301 (a) Any donor of prescription drugs or supplies, or any
302 participant in the program, who exercises reasonable care in
303 donating, accepting, distributing, or dispensing prescription
304 drugs or supplies under the program, and the rules adopted
305 pursuant thereto, is immune from civil or criminal liability and
306 from professional disciplinary action of any kind for any
307 injury, death, or loss to person or property relating to such
308 activities.

309 (b) A pharmaceutical manufacturer who exercises reasonable
310 care is not liable for any claim or injury arising from the
311 transfer of any prescription drug under this section, including
312 but not limited to, liability for failure to transfer or
313 communicate product or consumer information regarding the
314 transferred drug, including the expiration date of the
315 transferred drug.

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

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

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

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

327 (14) DIRECT-SUPPORT ORGANIZATION.-The department may
328 establish a direct-support organization to provide assistance,
329 funding, and promotional support for the activities authorized



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330 for the program.

331 (a) Purposes and objectives.-The purposes and objectives of
332 the direct-support organization of the program must be
333 consistent with the goals of the department, in the best
334 interest of the state, and in accordance with the adopted goals
335 and mission of the department.

336 (b) Prohibition against lobbying.-The direct-support
337 organization is not considered a lobbying firm within the
338 meaning of s. 11.045. All expenditures of the direct-support
339 organization must be used for the program. No expenditures of
340 the direct-support organization may be used for the purpose of
341 lobbying as defined in s. 11.045.

342 (c) Contract.-The direct-support organization shall operate
343 under a written contract with the department. The contract must
344 provide for a submission by the direct-support organization to
345 the department, by each August 1, and posting on the direct-
346 support organization's and department's websites, the following
347 information:

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

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

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

352 4. The statutory authority or executive order that created
353 the direct-support organization.

354 5. A brief description of the direct-support organization's
355 mission and any results obtained by the direct-support
356 organization.

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



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

362 8. Certification by the department that the direct-support
363 organization is complying with the terms of the contract and
364 operating in a manner consistent with the goals and purposes of
365 the department and the best interest of the program and the
366 state. Such certification must be made annually and reported in
367 the official minutes of a meeting of the direct-support
368 organization.

369 9. The reversion, without penalty, of moneys and property
370 held in trust by the direct-support organization for the benefit
371 of the program to the state if the department ceases to exist;
372 or reversion to the department if the direct-support
373 organization is no longer approved to operate or ceases to
374 exist.

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

378 11. The disclosure of material provisions of the contract,
379 and the distinction between the department and the direct-
380 support organization, to donors of gifts, contributions, or
381 bequests, including such disclosure on all promotional and
382 fundraising publications.

383 12. All prescription drugs solicited by the direct-support
384 organization to be distributed to the centralized repository or
385 a local repository. The direct-support organization may not
386 possess any prescription drugs on behalf of the program.

387 (d) Board of directors.—The State Surgeon General shall



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388 appoint a board of directors of the direct-support organization.
389 The board of directors shall consist of at least 5 members, but
390 not more than 15 members, who serve at the pleasure of the State
391 Surgeon General. The board members must elect a chair from among
392 its members. Board members must serve without compensation but
393 may be entitled to reimbursement of travel and per diem expenses
394 in accordance with s. 112.061, if funds are available for this
395 purpose.

396 (e) Use of property.—The department may allow, without
397 charge, appropriate use of fixed property, facilities, and
398 personnel services of the department by the direct-support
399 organization, subject to this subsection. For the purposes of
400 this paragraph, the term “personnel services” includes full-time
401 or part-time personnel, as well as payroll processing services.

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

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

410 3. The department shall adopt rules prescribing the
411 procedures by which the direct-support organization is governed
412 and any conditions with which a direct-support organization must
413 comply to use property or facilities of the department.

414 (f) Deposit of funds.—Any moneys may be held in a separate
415 depository account in the name of the direct-support
416 organization and subject to the provisions of the contract with



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417 the department.

418 (g) Use of funds.-Funds designated for the direct-support
419 organization must be used for the enhancement of the projects of
420 the program and used in a manner consistent with that purpose.
421 Any administrative costs of running and promoting the purposes
422 of the corporation or program must be paid by private funds.

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

425 (i) Repeal.-This subsection shall stand repealed on October
426 1, 2023, unless reviewed and saved from repeal by the
427 Legislature.

428 (15) RULEMAKING.-The department shall adopt rules necessary
429 to implement the requirements of this section. When applicable,
430 the rules may provide for the use of electronic forms,
431 recordkeeping, and meeting by teleconference.

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

434 252.36 Emergency management powers of the Governor.-

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

437 (o) Waive the patient eligibility requirements of s.
438 465.1902.

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

440
441 ===== T I T L E A M E N D M E N T =====

442 And the title is amended as follows:

443 Delete everything before the enacting clause
444 and insert:

445 A bill to be entitled



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446 An act relating to the Prescription Drug Donation
447 Repository Program; creating s. 465.1902, F.S.;
448 providing a short title; creating the Prescription
449 Drug Donation Repository Program within the Department
450 of Health; providing purpose; authorizing the
451 department to contract with a third party to implement
452 and administer the program; providing definitions;
453 specifying entities that are eligible donors;
454 providing criteria for eligible donations; prohibiting
455 donations to specific patients; providing that certain
456 prescription drugs eligible for return to stock must
457 be credited to Medicaid under specified conditions and
458 are not program eligible; prohibiting the donation of
459 certain drugs pursuant to federal restrictions;
460 authorizing repositories to refuse to accept donations
461 of prescription drugs or supplies; providing
462 inspection, inventory, and storage requirements for
463 centralized and local repositories; requiring
464 inspection of donated prescription drugs and supplies
465 by a licensed pharmacist; requiring a local repository
466 to notify the centralized repository within a
467 specified timeframe after receiving a donation of
468 prescription drugs or supplies; authorizing a
469 centralized repository to redistribute prescription
470 drugs or supplies; requiring local repositories to
471 notify the department regarding participation in the
472 program; providing conditions for dispensing donated
473 prescription drugs and supplies to eligible patients;
474 requiring repositories to establish a protocol for



475 notifying recipients of a prescription drug recall;
476 providing for destruction of donated prescription
477 drugs in the event of a drug recall; providing
478 recordkeeping requirements; requiring the department
479 to maintain and publish a registry of participating
480 local repositories and available donated prescription
481 drugs and supplies; specifying certain notice to
482 patients; providing immunity from civil and criminal
483 liability for participants under certain
484 circumstances; authorizing the department to establish
485 a direct-support organization to provide assistance
486 funding and promotional support for program
487 activities; specifying direct-support organization
488 purposes and objectives; prohibiting such direct-
489 support organization from lobbying and specifying that
490 such direct-support organization is not a lobbying
491 firm; specifying that the direct-support organization
492 must operate under contract with the department;
493 specifying required contract terms; providing for the
494 direct-support organization board of directors;
495 specifying the membership of such board; specifying
496 requirements relating to a direct-support
497 organization's use of department property; specifying
498 requirements for the deposit of funds by the direct-
499 support organization; providing for audits of a
500 direct-support organization; specifying a repeal,
501 unless reviewed and saved from repeal by the
502 Legislature on a specified date; requiring the
503 department to adopt rules; amending s. 252.36, F.S.;



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504 authorizing the Governor to waive the patient
505 eligibility requirements of s. 465.1902, F.S., during
506 a declared state of emergency; providing an effective
507 date.