

By 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; 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

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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; authorizing a repository to charge the
44 patient a nominal handling fee for the preparation and
45 dispensing of prescription drugs or supplies under the
46 program; requiring repositories to establish a
47 protocol for notifying recipients of a prescription
48 drug recall; providing for destruction of donated
49 prescription drugs under certain circumstances;
50 providing recordkeeping requirements; requiring the
51 centralized repository to submit an annual report to
52 the department; requiring the department or contractor
53 to establish, maintain, and publish a registry of
54 participating local repositories and available donated
55 prescription drugs and supplies; requiring the
56 department to publish certain information and forms on
57 its website; providing immunity from civil and
58 criminal liability and from professional disciplinary

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59 action for participants under certain circumstances;
60 providing immunity to pharmaceutical manufacturers,
61 under certain circumstances, from any claim or injury
62 arising from the donation of any prescription drug or
63 supply under the program; requiring dispensers to
64 provide certain notice to patients; authorizing the
65 department to establish a direct-support organization
66 to provide assistance, funding, and promotional
67 support for program activities; providing
68 organizational requirements for a direct-support
69 organization; specifying direct-support organization
70 purposes and objectives; prohibiting the direct-
71 support organization from lobbying; specifying that
72 the direct-support organization is not a lobbying
73 firm; prohibiting the direct-support organization from
74 possessing prescription drugs on behalf of the
75 program; providing limitations on expenditures of such
76 direct-support organizations; specifying that the
77 direct-support organization must operate under
78 contract with the department; specifying required
79 contract terms; providing for the direct-support
80 organization board of directors; specifying the
81 board's membership requirements; specifying
82 requirements and requiring the department to adopt
83 rules relating to a direct-support organization's use
84 of department property; specifying requirements for
85 the deposit and use of funds by the direct-support
86 organization; providing for annual audits of a direct-
87 support organization; providing for future legislative

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88 review and repeal of provisions relating to the
89 direct-support organization; requiring the department
90 to adopt rules; amending s. 252.36, F.S.; authorizing
91 the Governor to waive program patient eligibility
92 requirements during a declared state of emergency;
93 providing an effective date.
94

95 Be It Enacted by the Legislature of the State of Florida:
96

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

99 465.1902 Prescription Drug Donation Repository Program.—

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

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

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

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

111 (c) “Contractor” means the third-party vendor approved by
112 the department to implement and administer the program as
113 authorized in subsection (4).

114 (d) “Controlled substance” means any substance listed under
115 Schedule II, Schedule III, Schedule IV, or Schedule V of s.
116 893.03.

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

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

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

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

127 (i) "Free clinic" means a clinic that delivers only medical
128 diagnostic services or nonsurgical medical treatment free of
129 charge to low-income recipients.

130 (j) "Health care practitioner" or "practitioner" means a
131 practitioner licensed under this chapter, chapter 458, chapter
132 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

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

143 (m) "Nonprofit health clinic" means a nonprofit legal
144 entity that provides medical care to patients who are indigent,
145 uninsured, or underinsured. The term includes, but is not

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146 limited to, a federally qualified health center as defined in 42
147 U.S.C. s. 1396d(1)(2)(B) and a rural health clinic as defined in
148 42 U.S.C. s. 1396d(1)(1).

149 (n) "Nursing home facility" has the same meaning as in s.
150 400.021.

151 (o) "Prescriber" means a health care practitioner who,
152 within the scope of his or her practice act, is authorized to
153 prescribe medicinal drugs.

154 (p) "Prescription drug" has the same meaning as the term
155 "medicinal drugs" or "drugs," as those terms are defined in s.
156 465.003(8), but does not include controlled substances or cancer
157 drugs donated under s. 499.029.

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

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

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

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

172 (u) "Uninsured" means a person who has no third-party
173 insurance and is not eligible to receive prescription drugs or
174 supplies through the Medicaid program or any other prescription

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175 drug program funded in whole or in part by the Federal
 176 Government.

177 (3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM;
 178 CREATION; PURPOSE.—The Prescription Drug Donation Repository
 179 Program is created within the department for the purpose of
 180 authorizing and facilitating the donation of prescription drugs
 181 and supplies to eligible patients.

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

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

188 (a) Nursing home facilities with closed drug delivery
 189 systems.

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

192 (c) Hospitals with closed drug delivery systems.

193 (d) Pharmacies.

194 (e) Drug manufacturers or wholesale distributors.

195 (f) Medical device manufacturers or suppliers.

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

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

201 (a) Only prescription drugs and supplies that have been
 202 approved for medical use in the United States and that meet the
 203 criteria for donation established by this section may be

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204 accepted for donation under the program. Donations must be made
205 on the premises of the centralized repository or a local
206 repository to a person designated by the repository. A drop box
207 may not be used to accept donations.

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

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

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

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

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

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

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

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

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

232 (d) Prescription drugs or supplies may not be donated to a

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233 specific patient.

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

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

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

245 (7) INSPECTION AND STORAGE.—

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

250 (b) The inspecting pharmacist must sign an inspection
251 record on a form prescribed by the department by rule which
252 verifies that the prescription drugs and supplies meet the
253 criteria of subsections (5) and (6) and must attach the record
254 to the inventory required by paragraph (d). A local repository
255 that receives drugs and supplies from the centralized repository
256 is not required to reinspect them.

257 (c) The centralized repository and local repositories shall
258 store donated prescription drugs and supplies in a secure
259 storage area under the environmental conditions specified by the
260 manufacturer or the United States Pharmacopeia for the
261 respective prescription drugs or supplies. Donated prescription

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262 drugs and supplies may not be stored with other inventory. A
263 local repository shall quarantine donated prescription drugs or
264 supplies until they are inspected and approved for dispensing
265 under this section.

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

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

274 (f) The centralized repository may redistribute
275 prescription drugs and supplies by transferring them to or from
276 the centralized repository and a local repository, as needed. A
277 local repository that receives donated prescription drugs or
278 supplies may, with authorization from the centralized
279 repository, distribute the prescription drugs or supplies to
280 another local repository.

281 (8) PROGRAM PARTICIPATION.—

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

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

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291 including the name of the issuing agency.

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

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

299 (b) A local repository may withdraw from participation in
300 the program at any time by providing written notice to the
301 department or contractor, as appropriate, on a form prescribed
302 by the department by rule. The department shall adopt rules
303 addressing the disposition of prescription drugs and supplies in
304 the possession of the withdrawing local repository.

305 (9) DISPENSING REQUIREMENTS; PROHIBITIONS.-

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

311 1. The name, street address, and telephone number of the
312 eligible patient.

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

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

318 (b) Upon receipt of a completed and signed intake
319 collection form, the local repository shall issue him or her a

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320 program identification card, which is valid for 1 year after its
321 date of issuance. The card must be in a form prescribed by the
322 department by rule.

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

326 (d) A dispenser may dispense donated prescription drugs or
327 supplies only to an eligible patient who has a program
328 identification card or who has submitted a completed intake
329 collection form.

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

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

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

336 (h) A dispenser of donated prescription drugs or supplies
337 may not submit a claim or otherwise seek reimbursement from any
338 public or private third-party payor for donated prescription
339 drugs or supplies dispensed under this program. However, a
340 repository may charge the patient a nominal handling fee,
341 established by department rule, for the preparation and
342 dispensing of prescription drugs or supplies under the program.

343 (10) RECALLED PRESCRIPTION DRUGS AND SUPPLIES.—

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

347 (b) Local repositories shall destroy all recalled or
348 expired prescription drugs and all prescription drugs that are

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349 not suitable for dispensing in the repository. Local
350 repositories must complete a destruction information form for
351 all such drugs, in accordance with department rule.

352 (11) RECORDKEEPING.—

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

356 (b) All required records must be maintained in accordance
357 with any applicable practice act. Local repositories shall
358 submit these records quarterly to the centralized repository for
359 data collection, and the centralized repository shall submit
360 these records and the collected data in annual reports to the
361 department.

362 (12) REGISTRIES; PUBLICATION OF FORMS.—

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

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

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

377 (a) Any donor of prescription drugs or supplies and any

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378 participant in the program who exercises reasonable care in
379 donating, accepting, distributing, or dispensing prescription
380 drugs or supplies under the program is immune from civil or
381 criminal liability and from professional disciplinary action by
382 the state for any injury, death, or loss to person or property
383 relating to such activities.

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

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

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

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

398 (c) The eligible patient is not required to pay for the
399 prescription drug, but may be required to pay a nominal handling
400 fee, which may not exceed the amount established by department
401 rule.

402 (15) DIRECT-SUPPORT ORGANIZATION.—The department may
403 establish a direct-support organization to provide assistance,
404 funding, and promotional support for the activities authorized
405 under the act.

406 (a) Entity organization.—The direct-support organization

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407 must operate in accordance with s. 20.058 and is:

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

411 2. Organized and operated to conduct programs and
412 activities; raise funds and request and receive grants, gifts,
413 and bequests of moneys; acquire, receive, hold, and invest, in
414 its own name, securities, funds, objects of value, or other
415 property, either real or personal; and make expenditures or
416 provide funding to or for the direct or indirect benefit of the
417 program.

418 (b) Purposes and objectives.—The purposes and objectives of
419 the direct-support organization must be consistent with the
420 goals of the department, in the best interest of the state, and
421 in accordance with the adopted goals and the mission of the
422 department.

423 (c) Prohibition against lobbying.—The direct-support
424 organization is not considered a lobbying firm, as that term is
425 defined in s. 11.045(1). All expenditures of the direct-support
426 organization must be directly related to program administration
427 within the requirements of this section. Funds of the direct-
428 support organization may not be used for the purpose of
429 lobbying, as that term is defined in s. 11.045(1).

430 (d) Possession of prescription drugs.—The direct-support
431 organization may not possess any prescription drugs on behalf of
432 the program.

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

435 1. The contract must require the direct-support

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436 organization to submit to the department, annually by August 1,
437 the following information, which must be posted on the websites
438 of the direct-support organization and the department:

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

441 b. A proposed annual budget for the approval of the
442 department.

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

444 d. The statutory authority or executive order that created
445 the direct-support organization.

446 e. A brief description of the direct-support organization's
447 mission and any results obtained by the direct-support
448 organization.

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

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

454 h. Certification by the department that the direct-support
455 organization is complying with the terms of the contract and
456 operating in a manner consistent with the goals and purposes of
457 the department and the best interest of the program and the
458 state. Such certification must be made annually and reported in
459 the official minutes of a meeting of the board of directors of
460 the direct-support organization.

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

462 a. The reversion without penalty to the department, or to
463 the state if the department ceases to exist, of all moneys and
464 property held in trust by the direct-support organization for

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465 the benefit of the program if the direct-support organization
466 ceases to exist or if the contract is terminated.

467 b. A disclosure of material provisions of the contract and
468 the distinction between the department and the direct-support
469 organization to appear on all promotional and fundraising
470 publications.

471 c. A list of prescription drugs solicited by the direct-
472 support organization for distribution to the centralized
473 repository or a local repository.

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

482 (g) Use of property.—The department may allow, without
483 charge, appropriate use of fixed property, facilities, and
484 personnel services of the department by the direct-support
485 organization for purposes related to the program. For purposes
486 of this paragraph, the term "personnel services" includes full-
487 time or part-time personnel, as well as payroll processing
488 services.

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

492 2. The department may not allow the use of any fixed
493 property or facilities of the department by the direct-support

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494 organization if the organization does not provide equal
495 membership and employment opportunities to all persons
496 regardless of race, color, religion, sex, age, or national
497 origin.

498 3. The department shall adopt rules prescribing the
499 procedures by which the direct-support organization is governed
500 and any conditions with which a direct-support organization must
501 comply to use property or facilities of the department.

502 (h) Deposit of funds.—Any moneys of the direct-support
503 organization may be held in a separate depository account in the
504 name of the organization and subject to the provisions of the
505 organization's contract with the department.

506 (i) Use of funds.—Funds designated for the direct-support
507 organization must be used for the enhancement of program
508 projects and in a manner consistent with that purpose. Any
509 administrative costs of running and promoting the purposes of
510 the organization or program must be paid by private funds.

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

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

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

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

521 252.36 Emergency management powers of the Governor.—

522 (5) In addition to any other powers conferred upon the

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523 Governor by law, she or he may:

524 (o) Waive the patient eligibility requirements of s.

525 465.1902.

526 Section 3. This act shall take effect July 1, 2019.