

By the Committee on Health Policy; and Senator Book

588-01792-18

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1 A bill to be entitled
2 An act relating to the Prescription Drug Donation
3 Program; amending s. 499.029, F.S.; renaming the
4 Cancer Drug Donation Program as the Prescription Drug
5 Donation Program; authorizing the donation of
6 prescription drugs, including cancer drugs, and
7 supplies to eligible patients; revising definitions;
8 authorizing nursing home facilities to participate in
9 the program; providing an effective date.

10
11 Be It Enacted by the Legislature of the State of Florida:

12
13 Section 1. Section 499.029, Florida Statutes, is amended to
14 read:

15 499.029 Prescription ~~Cancer~~ Drug Donation Program.—

16 (1) This section may be cited as the "Prescription ~~Cancer~~
17 Drug Donation Program Act."

18 (2) There is created a Prescription ~~Cancer~~ Drug Donation
19 Program within the department for the purpose of authorizing and
20 facilitating the donation of prescription ~~cancer~~ drugs and
21 supplies to eligible patients.

22 (3) As used in this section:

23 (a) "Cancer drug" means a prescription drug that has been
24 approved under s. 505 of the Federal Food, Drug, and Cosmetic
25 Act and is used to treat cancer or its side effects or is used
26 to treat the side effects of a prescription drug used to treat
27 cancer or its side effects. The term "~~Cancer drug~~" does not
28 include a substance listed in Schedule II, Schedule III,
29 Schedule IV, or Schedule V of s. 893.03.

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30 (b) "Closed drug delivery system" means a system in which
31 the actual control of the unit-dose medication package is
32 maintained by the facility rather than by the individual
33 patient.

34 (c) "Donor" means a patient or patient representative who
35 donates prescription ~~cancer~~ drugs or supplies needed to
36 administer prescription ~~cancer~~ drugs that have been maintained
37 within a closed drug delivery system; health care facilities,
38 nursing home facilities ~~homes~~, hospices, or hospitals with
39 closed drug delivery systems; or pharmacies, drug manufacturers,
40 medical device manufacturers or suppliers, or wholesalers of
41 drugs or supplies, in accordance with this section. The term
42 ~~"Donor"~~ includes a physician licensed under chapter 458 or
43 chapter 459 who receives prescription ~~cancer~~ drugs or supplies
44 directly from a drug manufacturer, wholesale distributor, or
45 pharmacy.

46 (d) "Eligible patient" means a person who the department
47 determines is eligible to receive prescription ~~cancer~~ drugs from
48 the program.

49 (e) "Participant facility" means a hospital that operates a
50 class II institutional ~~hospital~~ pharmacy or a nursing home
51 facility licensed under part II of chapter 400 with a closed
52 drug delivery system that has elected to participate in the
53 program and that accepts donated prescription ~~cancer~~ drugs and
54 supplies under the rules adopted by the department for the
55 program.

56 (f) "Prescribing practitioner" means a physician licensed
57 under chapter 458 or chapter 459 or any other medical
58 professional with authority under state law to prescribe

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59 prescription drugs ~~cancer medication~~.

60 (g) "Prescription drug" has the same meaning as provided in
61 s. 499.003, and includes cancer drugs. The term does not include
62 a substance listed in Schedule II, Schedule III, Schedule IV, or
63 Schedule V of s. 893.03.

64 (h) ~~(g)~~ "Program" means the Prescription ~~Cancer~~ Drug
65 Donation Program created by this section.

66 (i) ~~(h)~~ "Supplies" means any supplies used in the
67 administration of a prescription ~~cancer~~ drug.

68 (4) Any donor may donate prescription ~~cancer~~ drugs or
69 supplies to a participant facility that elects to participate in
70 the program and meets criteria established by the department for
71 such participation. Prescription ~~Cancer~~ drugs or supplies may
72 not be donated to a specific ~~cancer~~ patient, and donated drugs
73 or supplies may not be resold by the program. Prescription
74 ~~Cancer~~ drugs billed to and paid for by Medicaid in long-term
75 care facilities that are eligible for return to stock under
76 federal Medicaid regulations shall be credited to Medicaid and
77 are not eligible for donation under the program. A participant
78 facility may provide dispensing and consulting services to
79 individuals who are not patients of the hospital or nursing home
80 facility.

81 (5) The prescription ~~cancer~~ drugs or supplies donated to
82 the program may be prescribed only by a prescribing practitioner
83 for use by an eligible patient and may be dispensed only by a
84 pharmacist.

85 (6) (a) A prescription ~~cancer~~ drug may only be accepted or
86 dispensed under the program if the drug is in its original,
87 unopened, sealed container, or in a tamper-evident unit-dose

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88 packaging, except that a prescription ~~cancer~~ drug packaged in
89 single-unit doses may be accepted and dispensed if the outside
90 packaging is opened but the single-unit-dose packaging is
91 unopened with tamper-resistant packaging intact.

92 (b) A prescription ~~cancer~~ drug may not be accepted or
93 dispensed under the program if the drug bears an expiration date
94 that is less than 6 months after the date the drug was donated
95 or if the drug appears to have been tampered with or mislabeled
96 as determined in paragraph (c).

97 (c) Prior to being dispensed to an eligible patient, the
98 prescription ~~cancer~~ drug or supplies donated under the program
99 shall be inspected by a pharmacist to determine that the drug
100 and supplies do not appear to have been tampered with or
101 mislabeled.

102 (d) A dispenser of donated prescription ~~cancer~~ drugs or
103 supplies may not submit a claim or otherwise seek reimbursement
104 from any public or private third-party payor for donated
105 prescription ~~cancer~~ drugs or supplies dispensed to any patient
106 under the program, and a public or private third-party payor is
107 not required to provide reimbursement to a dispenser for donated
108 prescription ~~cancer~~ drugs or supplies dispensed to any patient
109 under the program.

110 (7) (a) A donation of prescription ~~cancer~~ drugs or supplies
111 shall be made only at a participant facility. A participant
112 facility may decline to accept a donation. A participant
113 facility that accepts donated prescription ~~cancer~~ drugs or
114 supplies under the program shall comply with all applicable
115 provisions of state and federal law relating to the storage and
116 dispensing of the donated prescription ~~cancer~~ drugs or supplies.

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117 (b) A participant facility that voluntarily takes part in
118 the program may charge a handling fee sufficient to cover the
119 cost of preparation and dispensing of prescription ~~cancer~~ drugs
120 or supplies under the program. The fee shall be established in
121 rules adopted by the department.

122 (8) The department, upon the recommendation of the Board of
123 Pharmacy, shall adopt rules to carry out the provisions of this
124 section. ~~Initial rules under this section shall be adopted no~~
125 ~~later than 90 days after the effective date of this act.~~ The
126 rules shall include, but not be limited to:

127 (a) Eligibility criteria, including a method to determine
128 priority of eligible patients under the program.

129 (b) Standards and procedures for participant facilities
130 that accept, store, distribute, or dispense donated prescription
131 ~~cancer~~ drugs or supplies.

132 (c) Necessary forms for administration of the program,
133 including, but not limited to, forms for use by entities that
134 donate, accept, distribute, or dispense prescription ~~cancer~~
135 drugs or supplies under the program.

136 (d) The maximum handling fee that may be charged by a
137 participant facility that accepts and distributes or dispenses
138 donated prescription ~~cancer~~ drugs or supplies.

139 (e) Categories of prescription ~~cancer~~ drugs and supplies
140 that the program will accept for dispensing; however, the
141 department may exclude any drug based on its therapeutic
142 effectiveness or high potential for abuse or diversion.

143 (f) Maintenance and distribution of the participant
144 facility registry established in subsection (10).

145 (9) A person who is eligible to receive prescription ~~cancer~~

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146 drugs or supplies under the state Medicaid program or under any
147 other prescription drug program funded in whole or in part by
148 the state, by any other prescription drug program funded in
149 whole or in part by the Federal Government, or by any other
150 prescription drug program offered by a third-party insurer,
151 unless benefits have been exhausted, or a certain prescription
152 ~~cancer~~ drug or supply is not covered by the prescription drug
153 program, is ineligible to participate in the program created
154 under this section.

155 (10) The department shall establish and maintain a
156 participant facility registry for the program. The participant
157 facility registry shall include the participant facility's name,
158 address, and telephone number. The department shall make the
159 participant facility registry available on the department's
160 website to any donor wishing to donate prescription ~~cancer~~ drugs
161 or supplies to the program. The department's website shall also
162 contain links to prescription ~~cancer~~ drug manufacturers that
163 offer drug assistance programs or free medication.

164 (11) Any donor of prescription ~~cancer~~ drugs or supplies, or
165 any participant in the program, who exercises reasonable care in
166 donating, accepting, distributing, or dispensing prescription
167 ~~cancer~~ drugs or supplies under the program and the rules adopted
168 under this section shall be immune from civil or criminal
169 liability and from professional disciplinary action of any kind
170 for any injury, death, or loss to person or property relating to
171 such activities.

172 (12) A pharmaceutical manufacturer is not liable for any
173 claim or injury arising from the transfer of any prescription
174 ~~cancer~~ drug under this section, including, but not limited to,

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175 liability for failure to transfer or communicate product or
176 consumer information regarding the transferred drug, as well as
177 the expiration date of the transferred drug.

178 (13) If any conflict exists between the provisions in this
179 section and the provisions in this chapter or chapter 465, the
180 provisions in this section shall control the operation of the
181 Prescription ~~Cancer~~ Drug Donation Program.

182 Section 2. This act shall take effect July 1, 2018.