

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
 14 to 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.

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
50 | a 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
59 prescription drugs ~~cancer medication~~.

60 (g) "Prescription drug" has the same meaning as provided
61 in s. 499.003, and includes cancer drugs.

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

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

66 (4) Any donor may donate prescription ~~cancer~~ drugs or
67 supplies to a participant facility that elects to participate in
68 the program and meets criteria established by the department for
69 such participation. Prescription ~~Cancer~~ drugs or supplies may
70 not be donated to a specific ~~cancer~~ patient, and donated drugs
71 or supplies may not be resold by the program. Prescription
72 ~~Cancer~~ drugs billed to and paid for by Medicaid in long-term
73 care facilities that are eligible for return to stock under
74 federal Medicaid regulations shall be credited to Medicaid and
75 are not eligible for donation under the program. A participant

76 facility may provide dispensing and consulting services to
77 individuals who are not patients of the hospital or nursing home
78 facility.

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

83 (6) (a) A prescription ~~cancer~~ drug may only be accepted or
84 dispensed under the program if the drug is in its original,
85 unopened, sealed container, or in a tamper-evident unit-dose
86 packaging, except that a prescription ~~cancer~~ drug packaged in
87 single-unit doses may be accepted and dispensed if the outside
88 packaging is opened but the single-unit-dose packaging is
89 unopened with tamper-resistant packaging intact.

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

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

100 (d) A dispenser of donated prescription ~~cancer~~ drugs or

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

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

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

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

125 (a) Eligibility criteria, including a method to determine

126 priority of eligible patients under the program.

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

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

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

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

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

143 (9) A person who is eligible to receive prescription
144 ~~cancer~~ drugs or supplies under the state Medicaid program or
145 under any other prescription drug program funded in whole or in
146 part by the state, by any other prescription drug program funded
147 in whole or in part by the Federal Government, or by any other
148 prescription drug program offered by a third-party insurer,
149 unless benefits have been exhausted, or a certain prescription
150 ~~cancer~~ drug or supply is not covered by the prescription drug

151 program, is ineligible to participate in the program created
152 under this section.

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

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

170 (12) A pharmaceutical manufacturer is not liable for any
171 claim or injury arising from the transfer of any prescription
172 ~~cancer~~ drug under this section, including, but not limited to,
173 liability for failure to transfer or communicate product or
174 consumer information regarding the transferred drug, as well as
175 the expiration date of the transferred drug.

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

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