

By Senator Peaden

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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; revising definitions; expanding the
 6 drugs and supplies that may be donated under the
 7 program; expanding the types of facilities and
 8 practitioners that may participate in the program;
 9 conforming provisions to changes in terminology;
 10 removing obsolete language relating to the adoption of
 11 initial rules; providing an effective date.

12
 13 Be It Enacted by the Legislature of the State of Florida:

14
 15 Section 1. Section 499.029, Florida Statutes, is amended to
 16 read:

17 499.029 Prescription ~~Cancer~~ Drug Donation Program.—

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

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

24 (3) As used in this section, the term:

25 ~~(a) "Cancer drug" means a prescription drug that has been~~
 26 ~~approved under s. 505 of the federal Food, Drug, and Cosmetic~~
 27 ~~Act and is used to treat cancer or its side effects or is used~~
 28 ~~to treat the side effects of a prescription drug used to treat~~
 29 ~~cancer or its side effects. "Cancer drug" does not include a~~

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30 ~~substance listed in Schedule II, Schedule III, Schedule IV, or~~
31 ~~Schedule V of s. 893.03.~~

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

36 (b) "Dispensing practitioner" means a practitioner
37 registered under s. 465.0276.

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

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

53 (e) "Participant ~~facility~~" means a ~~class II hospital~~
54 pharmacy or dispensing practitioner that has elected to
55 participate in the program and that accepts donated prescription
56 ~~cancer~~ drugs and supplies under the rules adopted by the
57 department for the program.

58 (f) "Prescribing practitioner" means a physician licensed

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59 under chapter 458 or chapter 459 or any other medical
60 professional with authority under state law to prescribe drugs
61 ~~cancer medication~~.

62 (g) "Prescription drug" does not include a substance listed
63 in Schedule II, Schedule III, Schedule IV, or Schedule V of s.
64 893.03.

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

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

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

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

87 (6) (a) A prescription cancer drug may only be accepted or

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88 dispensed under the program if the drug is in its original,
89 unopened, sealed container, or in a tamper-evident unit-dose
90 packaging, except that a prescription cancer drug packaged in
91 single-unit doses may be accepted and dispensed if the outside
92 packaging is opened but the single-unit-dose packaging is
93 unopened with tamper-resistant packaging intact.

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

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

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

112 (7) (a) A donation of prescription cancer drugs or supplies
113 shall be made only at a participant's participant facility. A
114 participant ~~facility~~ may decline to accept a donation. A
115 participant ~~facility~~ that accepts donated prescription cancer
116 drugs or supplies under the program shall comply with all

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117 applicable provisions of state and federal law relating to the
118 storage and dispensing of the donated prescription ~~cancer~~ drugs
119 or supplies.

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

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

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

132 (b) Standards and procedures for participants ~~participant~~
133 ~~facilities~~ that accept, store, distribute, or dispense donated
134 prescription ~~cancer~~ drugs or supplies.

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

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

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

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146 (f) Maintenance and distribution of the participant
147 ~~facility~~ registry established in subsection (10).

148 (9) A person who is eligible to receive prescription cancer
149 drugs or supplies under the state Medicaid program or under any
150 other prescription drug program funded in whole or in part by
151 the state, by any other prescription drug program funded in
152 whole or in part by the Federal Government, or by any other
153 prescription drug program offered by a third-party insurer,
154 unless benefits have been exhausted, ~~r~~ or a certain prescription
155 ~~cancer~~ drug or supply is not covered by the prescription drug
156 program, is ineligible to participate in the program created
157 under this section.

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

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

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175 such activities.

176 (12) A pharmaceutical manufacturer is not liable for any
177 claim or injury arising from the transfer of any prescription
178 ~~cancer~~ drug under this section, including, but not limited to,
179 liability for failure to transfer or communicate product or
180 consumer information regarding the transferred drug, as well as
181 the expiration date of the transferred drug.

182 (13) If any conflict exists between the provisions in this
183 section and the provisions in this chapter or chapter 465, the
184 provisions in this section shall control the operation of the
185 ~~Cancer Drug Donation~~ program.

186 Section 2. This act shall take effect July 1, 2009.