

1 A bill to be entitled
 2 An act relating to the Prescription Drug Donation Program;
 3 amending s. 499.029, F.S.; renaming the Cancer Drug
 4 Donation Program as the Prescription Drug Donation
 5 Program; revising definitions; expanding the drugs and
 6 supplies that may be donated under the program; expanding
 7 the types of facilities and practitioners that may
 8 participate in the program; conforming provisions to
 9 changes in terminology; providing an effective date.

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

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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 ~~of Health~~ for the purpose of
 20 authorizing and facilitating the donation of prescription ~~cancer~~
 21 drugs and 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. "Cancer drug" does not include a~~

28 ~~substance listed in Schedule II, Schedule III, Schedule IV, or~~
 29 ~~Schedule V of s. 893.03.~~

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

34 (b) "Dispensing practitioner" means a practitioner
 35 registered under s. 465.0276.

36 ~~(c)~~ "~~Department~~" means ~~the Department of Health.~~

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

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

52 (e)~~(f)~~ "Health care facility" means a health care facility
 53 licensed under chapter 395.

54 ~~(g)~~ "~~Health care clinic~~" means a ~~health care clinic~~
 55 ~~licensed under part X of chapter 400.~~

56 (f)~~(h)~~ "Hospice" means a corporation licensed under part
 57 IV of chapter 400.

58 (g)~~(i)~~ "Hospital" means a facility as defined in s.
 59 395.002 and licensed under chapter 395.

60 (h)~~(j)~~ "Nursing home" means a facility licensed under part
 61 II of chapter 400.

62 (i)~~(k)~~ "Participant ~~facility~~" means a ~~class II hospital~~
 63 pharmacy or dispensing practitioner that has elected to
 64 participate in the program and that accepts donated prescription
 65 ~~cancer~~ drugs and supplies under the rules adopted by the
 66 department for the program.

67 (j)~~(l)~~ "Pharmacist" means a person licensed under chapter
 68 465.

69 (k)~~(m)~~ "Pharmacy" means an entity licensed under chapter
 70 465.

71 (l)~~(n)~~ "Prescribing practitioner" means a physician
 72 licensed under chapter 458 or chapter 459 or any other medical
 73 professional with authority under state law to prescribe drugs
 74 ~~cancer medication~~.

75 (m)~~(o)~~ "Prescription drug" does not include a substance
 76 listed in Schedule II, Schedule III, Schedule IV, or Schedule V
 77 of s. 893.03 ~~means a drug as defined in s. 465.003(8)~~.

78 (n)~~(p)~~ "Program" means the Prescription Cancer Drug
 79 Donation Program created by this section.

80 (o)~~(q)~~ "Supplies" means any supplies used in the
 81 administration of a prescription cancer drug.

82 (4) Any donor may donate prescription cancer drugs or
 83 supplies to a participant ~~facility~~ that elects to participate in

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84 the program and meets criteria established by the department for
85 such participation. Prescription ~~Cancer~~ drugs or supplies may
86 not be donated to a specific ~~cancer~~ patient, and donated
87 prescription drugs or supplies may not be resold by the
88 participant ~~program~~. Prescription ~~Cancer~~ drugs billed to and
89 paid for by Medicaid in long-term care facilities that are
90 eligible for return to stock under federal Medicaid regulations
91 shall be credited to Medicaid and are not eligible for donation
92 under the program. A participant ~~facility~~ may provide dispensing
93 and counseling ~~consulting~~ services to an eligible patient
94 ~~individuals~~ who is ~~are~~ not a patient ~~patients~~ of the participant
95 ~~hospital~~.

96 (5) The prescription ~~cancer~~ drugs or supplies donated to
97 the program may be prescribed only by a prescribing practitioner
98 for use by an eligible patient and may be dispensed only by a
99 pharmacist or a dispensing practitioner.

100 (6) (a) A prescription ~~cancer~~ drug may only be accepted or
101 dispensed under the program if the drug is in its original,
102 unopened, sealed container, or in a tamper-evident unit-dose
103 packaging, except that a prescription ~~cancer~~ drug packaged in
104 single-unit doses may be accepted and dispensed if the outside
105 packaging is opened but the single-unit-dose packaging is
106 unopened with tamper-resistant packaging intact.

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

112 (c) Prior to being dispensed to an eligible patient, the
 113 prescription ~~cancer~~ drug or supplies donated under the program
 114 shall be inspected by a pharmacist or dispensing practitioner to
 115 determine that the drug and supplies do not appear to have been
 116 tampered with or mislabeled.

117 (d) A dispenser of donated prescription ~~cancer~~ drugs or
 118 supplies may not submit a claim or otherwise seek reimbursement
 119 from any public or private third-party payor for donated
 120 prescription ~~cancer~~ drugs or supplies dispensed to any patient
 121 under the program, and a public or private third-party payor is
 122 not required to provide reimbursement to a dispenser for donated
 123 prescription ~~cancer~~ drugs or supplies dispensed to any patient
 124 under the program.

125 (7) (a) A donation of prescription ~~cancer~~ drugs or supplies
 126 shall be made only at a participant's ~~participant~~ facility. A
 127 participant ~~facility~~ may decline to accept a donation. A
 128 participant ~~facility~~ that accepts donated prescription ~~cancer~~
 129 drugs or supplies under the program shall comply with all
 130 applicable provisions of state and federal law relating to the
 131 storage and dispensing of the donated prescription ~~cancer~~ drugs
 132 or supplies.

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

138 (8) The department, upon the recommendation of the Board
 139 of Pharmacy, shall adopt rules to carry out the provisions of

140 this section. Initial rules under this section shall be adopted
 141 no later than 90 days after the effective date of this act. The
 142 rules shall include, but not be limited to:

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

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

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

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

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

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

161 (9) A person who is eligible to receive prescription
 162 ~~cancer~~ drugs or supplies under the state Medicaid program or
 163 under any other prescription drug program funded in whole or in
 164 part by the state, by any other prescription drug program funded
 165 in whole or in part by the Federal Government, or by any other
 166 prescription drug program offered by a third-party insurer,
 167 unless benefits have been exhausted, or a certain prescription

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168 ~~ancer~~ drug or supply is not covered by the prescription drug
169 program, is ineligible to participate in the program created
170 under this section.

171 (10) The department shall establish and maintain a
172 participant ~~facility~~ registry for the program. The participant
173 ~~facility~~ registry shall include the participant's ~~participant~~
174 ~~facility's~~ name, address, and telephone number. The department
175 shall make the participant ~~facility~~ registry available on the
176 department's website to any donor wishing to donate prescription
177 ~~ancer~~ drugs or supplies to the program. The department's
178 website shall also contain links to prescription ~~ancer~~ drug
179 manufacturers that offer drug assistance programs or free
180 medication.

181 (11) Any donor of prescription ~~ancer~~ drugs or supplies,
182 or any participant in the program, who exercises reasonable care
183 in donating, accepting, distributing, or dispensing prescription
184 ~~ancer~~ drugs or supplies under the program and the rules adopted
185 under this section shall be immune from civil or criminal
186 liability and from professional disciplinary action of any kind
187 for any injury, death, or loss to person or property relating to
188 such activities.

189 (12) A pharmaceutical manufacturer is not liable for any
190 claim or injury arising from the transfer of any prescription
191 ~~ancer~~ drug under this section, including, but not limited to,
192 liability for failure to transfer or communicate product or
193 consumer information regarding the transferred drug, as well as
194 the expiration date of the transferred drug.

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195 (13) If any conflict exists between the provisions in this
196 section and the provisions in this chapter or chapter 465, the
197 provisions in this section shall control the operation of the
198 ~~Cancer Drug Donation~~ program.

199 Section 2. This act shall take effect July 1, 2008.