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1 A bill to be entitled
 2 An act relating to the Prescription Drug Donation Program;
 3 amending s. 499.029, F.S.; expanding the drugs and
 4 supplies that may be donated under the program; expanding
 5 the types of facilities that may participate in the
 6 program; providing an effective date.

7
 8 Be It Enacted by the Legislature of the State of Florida:

9
 10 Section 1. Section 499.029, Florida Statutes, is amended
 11 to read:

12 499.029 Prescription Cancer Drug Donation Program.--

13 (1) This section may be cited as the "Prescription Cancer
 14 Drug Donation Program Act."

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

19 (3) As used in this section:

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

27 (a) ~~(b)~~ "Closed drug delivery system" means a system in
 28 which the actual control of the unit-dose medication package is

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29 maintained by the facility rather than by the individual
30 patient.

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

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

43 (c) ~~(e)~~ "Eligible patient" means a person who the
44 department determines is eligible to receive prescription ~~cancer~~
45 drugs from the program.

46 (d) ~~(f)~~ "Health care facility" means a health care facility
47 licensed under chapter 395.

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

50 (e) ~~(h)~~ "Hospice" means a corporation licensed under part
51 IV of chapter 400.

52 (f) ~~(i)~~ "Hospital" means a facility as defined in s.
53 395.002 and licensed under chapter 395.

54 (g) ~~(j)~~ "Nursing home" means a facility licensed under part
55 II of chapter 400.

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

61 (i) ~~(l)~~ "Pharmacist" means a person licensed under chapter
 62 465.

63 (j) ~~(m)~~ "Pharmacy" means an entity licensed under chapter
 64 465.

65 (k) ~~(n)~~ "Prescribing practitioner" means a physician
 66 licensed under chapters ~~chapter~~ 458 or 459 or any other medical
 67 professional with authority under state law to prescribe drugs
 68 ~~cancer medication~~.

69 (l) ~~(o)~~ "Prescription drug" does not include a substance
 70 listed in Schedule II, Schedule III, Schedule IV, or Schedule V
 71 of s. 893.03. ~~means a drug as defined in s. 465.003(8).~~

72 (m) ~~(p)~~ "Program" means the Prescription Cancer Drug
 73 Donation Program created by this section.

74 (n) ~~(q)~~ "Supplies" means any supplies used in the
 75 administration of a prescription ~~cancer~~ drug.

76 (4) Any donor may donate ~~cancer~~ drugs or supplies to a
 77 participant ~~facility~~ that elects to participate in the program
 78 and meets criteria established by the department for such
 79 participation. Prescription Cancer ~~cancer~~ drugs or supplies may not be
 80 donated to a specific ~~cancer~~ patient, and donated prescription
 81 drugs or supplies may not be resold by the participant ~~program~~.
 82 Prescription Cancer ~~cancer~~ drugs billed to and paid for by Medicaid in
 83 long-term care facilities that are eligible for return to stock

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84 | under federal Medicaid regulations shall be credited to Medicaid
 85 | and are not eligible for donation under the program. A
 86 | participant ~~facility~~ may provide dispensing and consulting
 87 | services to an individual ~~individuals~~ who is ~~are~~ not a patient
 88 | ~~patients~~ of the participant-hospital.

89 | (5) The prescription ~~cancer~~ drugs or supplies donated to
 90 | the program may be prescribed only by a prescribing practitioner
 91 | for use by an eligible patient and may be dispensed only by a
 92 | pharmacist or a dispensing practitioner.

93 | (6) (a) A prescription ~~cancer~~ drug may only be accepted or
 94 | dispensed under the program if the drug is in its original,
 95 | unopened, sealed container, or in a tamper-evident unit-dose
 96 | packaging, except that a prescription ~~cancer~~ drug packaged in
 97 | single-unit doses may be accepted and dispensed if the outside
 98 | packaging is opened but the single-unit-dose packaging is
 99 | unopened with tamper-resistant packaging intact.

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

105 | (c) Prior to being dispensed to an eligible patient, the
 106 | prescription ~~cancer~~ drug or supplies donated under the program
 107 | shall be inspected by a pharmacist or dispensing practitioner to
 108 | determine that the drug and supplies do not appear to have been
 109 | tampered with or mislabeled.

110 | (d) A dispenser of donated prescription ~~cancer~~ drugs or
 111 | supplies may not submit a claim or otherwise seek reimbursement

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112 from any public or private third-party payor for donated
 113 prescription ~~cancer~~ drugs or supplies dispensed to any patient
 114 under the program, and a public or private third-party payor is
 115 not required to provide reimbursement to a dispenser for donated
 116 prescription ~~cancer~~ drugs or supplies dispensed to any patient
 117 under the program.

118 (7) (a) A donation of prescription ~~cancer~~ drugs or supplies
 119 shall be made only at a participant's ~~participant~~ facility. A
 120 participant ~~facility~~ may decline to accept a donation. A
 121 participant ~~facility~~ that accepts donated prescription ~~cancer~~
 122 drugs or supplies under the program shall comply with all
 123 applicable provisions of state and federal law relating to the
 124 storage and dispensing of the donated prescription ~~cancer~~ drugs
 125 or supplies.

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

131 (8) The department, upon the recommendation of the Board
 132 of Pharmacy, shall adopt rules to carry out the provisions of
 133 this section. Initial rules under this section shall be adopted
 134 no later than 90 days after the effective date of this act. The
 135 rules shall include, but not be limited to:

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

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

141 (c) Necessary forms for administration of the program,
 142 including, but not limited to, forms for use by entities that
 143 donate, accept, distribute, or dispense prescription cancer
 144 drugs or supplies under the program.

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

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

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

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

164 (10) The department shall establish and maintain a
 165 participant ~~facility~~ registry for the program. The participant

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166 ~~facility~~ registry shall include the participant's ~~participant~~
 167 ~~facility's~~ name, address, and telephone number. The department
 168 shall make the participant ~~facility~~ registry available on the
 169 department's website to any donor wishing to donate prescription
 170 ~~cancer~~ drugs or supplies to the program. The department's
 171 website shall also contain links to prescription ~~cancer~~ drug
 172 manufacturers that offer drug assistance programs or free
 173 medication.

174 (11) Any donor of prescription ~~cancer~~ drugs or supplies,
 175 or any participant in the program, who exercises reasonable care
 176 in donating, accepting, distributing, or dispensing prescription
 177 ~~cancer~~ drugs or supplies under the program and the rules adopted
 178 under this section shall be immune from civil or criminal
 179 liability and from professional disciplinary action of any kind
 180 for any injury, death, or loss to person or property relating to
 181 such activities.

182 (12) A pharmaceutical manufacturer is not liable for any
 183 claim or injury arising from the transfer of any prescription
 184 ~~cancer~~ drug under this section, including, but not limited to,
 185 liability for failure to transfer or communicate product or
 186 consumer information regarding the transferred drug, as well as
 187 the expiration date of the transferred drug.

188 (13) If any conflict exists between the provisions in this
 189 section and the provisions in this chapter or chapter 465, the
 190 provisions in this section shall control the operation of the
 191 ~~Cancer Drug Donation~~ program.

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