



29 ~~cancer or its side effects. "Cancer drug" does not include a~~  
 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

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56 ~~cancer~~ drugs and supplies under the rules adopted by the  
57 department for the program.

58 (f) "Prescribing practitioner" means a physician licensed  
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  
63 listed in Schedule II, Schedule III, Schedule IV, or Schedule V  
64 of s. 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  
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  
100 patient, the prescription ~~cancer~~ drug or supplies donated under  
101 the 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

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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  
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  
126 of Pharmacy, shall adopt rules to carry out the provisions of  
127 this section. ~~Initial rules under this section shall be adopted~~  
128 ~~no 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

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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.

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  
149 ~~cancer~~ drugs or supplies under the state Medicaid program or  
150 under any other prescription drug program funded in whole or in  
151 part by the state, by any other prescription drug program funded  
152 in 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, 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

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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,  
169 or any participant in the program, who exercises reasonable care  
170 in 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  
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.