

## CHAMBER ACTION

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1 The Judiciary Committee recommends the following:

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3 **Council/Committee Substitute**

4 Remove the entire bill and insert:

5 A bill to be entitled

6 An act relating to the Cancer Drug Donation Program;  
7 creating s. 381.94, F.S.; providing a short title;  
8 creating the Cancer Drug Donation Program; providing a  
9 purpose; providing definitions; providing conditions for  
10 the donation of cancer drugs and supplies to the program;  
11 providing conditions for the acceptance of cancer drugs  
12 and supplies into the program, inspection of cancer drugs  
13 and supplies, and dispensing of cancer drugs and supplies  
14 to eligible patients; requiring a participant facility  
15 that accepts donated drugs and supplies through the  
16 program to comply with certain state and federal laws;  
17 authorizing a participant facility to charge fees under  
18 certain conditions; requiring the Department of Health,  
19 upon recommendation of the Board of Pharmacy, to adopt  
20 certain rules; providing for the ineligibility of certain  
21 persons to receive donated drugs; requiring the department  
22 to establish and maintain a participant facility registry;  
23 providing for the contents and availability of the

24 participant facility registry; providing immunity from  
 25 civil and criminal liability for donors or pharmaceutical  
 26 manufacturers in certain circumstances; providing that in  
 27 the event of conflict between the provisions in s. 381.94,  
 28 F.S., and provisions in ch. 465 or ch. 499, F.S., the  
 29 provisions in s. 381.94, F.S., shall control; providing an  
 30 appropriation; providing an effective date.

31

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

33

34 Section 1. Section 381.94, Florida Statutes, is created to  
 35 read:

36 381.94 Cancer Drug Donation Program.--

37 (1) This section may be cited as the "Cancer Drug Donation  
 38 Program Act."

39 (2) There is created a Cancer Drug Donation Program within  
 40 the Department of Health for the purpose of authorizing and  
 41 facilitating the donation of cancer drugs and supplies to  
 42 eligible patients.

43 (3) As used in this section:

44 (a) "Cancer drug" means a prescription drug that has been  
 45 approved under s. 505 of the federal Food, Drug, and Cosmetic  
 46 Act and is used to treat cancer or its side effects or is used  
 47 to treat the side effects of a prescription drug used to treat  
 48 cancer or its side effects. "Cancer drug" does not include a  
 49 substance listed in Schedule II, Schedule III, Schedule IV, or  
 50 Schedule V of s. 893.03.

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51 (b) "Closed drug delivery system" means a system in which  
52 the actual control of the unit-dose medication package is  
53 maintained by the facility rather than by the individual  
54 patient.

55 (c) "Department" means the Department of Health.

56 (d) "Donor" means a patient or patient representative who  
57 donates cancer drugs or supplies needed to administer cancer  
58 drugs that have been maintained within a closed drug delivery  
59 system; health care facilities, nursing homes, hospices, or  
60 hospitals with closed drug delivery systems; or pharmacies, drug  
61 manufacturers, medical device manufacturers or suppliers, or  
62 wholesalers of drugs or supplies, in accordance with this  
63 section. "Donor" includes a physician licensed under chapter 458  
64 or chapter 459 who receives cancer drugs or supplies directly  
65 from a drug manufacturer, drug wholesaler, or pharmacy.

66 (e) "Eligible patient" means a person who the department  
67 determines is eligible to receive cancer drugs from the program.

68 (f) "Health care facility" means a health care facility  
69 licensed under chapter 395.

70 (g) "Health care clinic" means a health care clinic  
71 licensed under part XIII of chapter 400.

72 (h) "Hospice" means a corporation licensed under part VI  
73 of chapter 400.

74 (i) "Hospital" means a facility as defined in s. 395.002  
75 and licensed under chapter 395.

76 (j) "Nursing home" means a facility licensed under part II  
77 of chapter 400.

78           (k) "Participant facility" means a class II hospital  
 79 pharmacy that has elected to participate in the program and that  
 80 accepts donated cancer drugs and supplies under the rules  
 81 adopted by the department for the program.

82           (l) "Pharmacist" means a person licensed under chapter  
 83 465.

84           (m) "Pharmacy" means an entity licensed under chapter 465.

85           (n) "Prescribing practitioner" means a physician licensed  
 86 under chapter 458 or any other medical professional with  
 87 authority under state law to prescribe cancer medication.

88           (o) "Prescription drug" means a drug as defined in s.  
 89 465.003 (8) .

90           (p) "Program" means the Cancer Drug Donation Program  
 91 created by this section.

92           (q) "Supplies" means any supplies used in the  
 93 administration of a cancer drug.

94           (4) Any donor may donate cancer drugs or supplies to a  
 95 participant facility that elects to participate in the program  
 96 and meets criteria established by the department for such  
 97 participation. Cancer drugs or supplies may not be donated to a  
 98 specific cancer patient, and donated drugs or supplies may not  
 99 be resold by the program. A participant facility may provide  
 100 dispensing and consulting services to individuals who are not  
 101 patients of the hospital.

102           (5) The cancer drugs or supplies donated to the program  
 103 may be prescribed only by a prescribing practitioner for use by  
 104 an eligible patient and may be dispensed only by a pharmacist.

105       (6) (a) A cancer drug may only be accepted or dispensed  
106 under the program if the drug is in its original, unopened,  
107 sealed container, or in a tamper-evident unit-dose packaging,  
108 except that a cancer drug packaged in single-unit doses may be  
109 accepted and dispensed if the outside packaging is opened but  
110 the single-unit-dose packaging is unopened with tamper-resistant  
111 packaging intact.

112       (b) A cancer drug may not be accepted or dispensed under  
113 the program if the drug bears an expiration date that is less  
114 than 6 months after the date the drug was donated or if the drug  
115 appears to have been tampered with or mislabeled as determined  
116 in paragraph (c).

117       (c) Prior to being dispensed to an eligible patient, the  
118 cancer drug or supplies donated under the program shall be  
119 inspected by a pharmacist to determine that the drug and  
120 supplies do not appear to have been tampered with or mislabeled.

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

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

133 relating to the storage and dispensing of the donated cancer  
134 drugs or supplies.

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

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

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

147 (b) Standards and procedures for participant facilities  
148 that accept, store, distribute, or dispense donated cancer drugs  
149 or supplies.

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

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

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

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

163 (9) A person who is eligible to receive cancer drugs or  
164 supplies under the state Medicaid program or under any other  
165 prescription drug program funded in whole or in part by the  
166 state, by any other prescription drug program funded in whole or  
167 in part by the Federal Government, or by any other prescription  
168 drug program offered by a third-party insurer, unless benefits  
169 have been exhausted, or a certain cancer drug or supply is not  
170 covered by the prescription drug program, is ineligible to  
171 participate in the program created under this section.

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

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

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

195        (13) If any conflict exists between the provisions in this  
196 section and the provisions in chapter 465 or chapter 499, the  
197 provisions in this section shall control the operation of the  
198 Cancer Drug Donation Program.

199        Section 2. There is hereby appropriated one full-time  
200 equivalent position at salary rate 42,715 and recurring funding  
201 from the General Revenue Fund in the sum of \$65,308 for fiscal  
202 year 2006-2007, for the purpose of implementing the Cancer Drug  
203 Donation Program under s. 381.94, Florida Statutes, as created  
204 by this act.

205        Section 3. This act shall take effect July 1, 2006.