

CHAMBER ACTION

1 The Health & Families Council recommends the following:

2
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. 499.029, 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

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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.
 28 499.029, F.S., and provisions in ch. 465 or ch. 499, F.S.,
 29 the provisions in s. 499.029, F.S., shall control;
 30 providing an appropriation; providing an effective date.
 31

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

33
 34 Section 1. Section 499.029, Florida Statutes, is created
 35 to read:

36 499.029 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.

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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. Cancer drugs billed to and paid for by
100 Medicaid in long-term care facilities that are eligible for
101 return to stock under federal Medicaid regulations shall be
102 credited to Medicaid and are not eligible for donation under the
103 program. A participant facility may provide dispensing and
104 consulting services to individuals who are not patients of the
105 hospital.

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

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

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

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

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

132 (7) (a) A donation of cancer drugs or supplies shall be
133 made only at a participant facility. A participant facility may

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134 decline to accept a donation. A participant facility that
135 accepts donated cancer drugs or supplies under the program shall
136 comply with all applicable provisions of state and federal law
137 relating to the storage and dispensing of the donated cancer
138 drugs or supplies.

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

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

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

151 (b) Standards and procedures for participant facilities
152 that accept, store, distribute, or dispense donated cancer drugs
153 or supplies.

154 (c) Necessary forms for administration of the program,
155 including, but not limited to, forms for use by entities that
156 donate, accept, distribute, or dispense cancer drugs or supplies
157 under the program.

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

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

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

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

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

185 (11) Any donor of cancer drugs or supplies, or any
186 participant in the program, who exercises reasonable care in
187 donating, accepting, distributing, or dispensing cancer drugs or
188 supplies under the program and the rules adopted under this

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189 section shall be immune from civil or criminal liability and
190 from professional disciplinary action of any kind for any
191 injury, death, or loss to person or property relating to such
192 activities.

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

199 (13) If any conflict exists between the provisions in this
200 section and the provisions in this chapter or chapter 465, the
201 provisions in this section shall control the operation of the
202 Cancer Drug Donation Program.

203 Section 2. There is hereby appropriated one full-time
204 equivalent position at salary rate 42,715 and recurring funding
205 from the Florida Drug, Device, and Cosmetic Trust Fund pursuant
206 to s. 499.057, Florida Statutes, in the sum of \$65,308 for
207 fiscal year 2006-2007, for the purpose of implementing the
208 Cancer Drug Donation Program under s. 499.029, Florida Statutes,
209 as created by this act.

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