

CHAMBER ACTION

1 The Health Care Appropriations Committee recommends the
2 following:

3
4 **Council/Committee Substitute**

5 Remove the entire bill and insert:

6 A bill to be entitled

7 An act relating to the Cancer Drug Donation Program;
8 creating s. 499.029, F.S.; providing a short title;
9 creating the Cancer Drug Donation Program; providing a
10 purpose; providing definitions; providing conditions for
11 the donation of cancer drugs and supplies to the program;
12 providing conditions for the acceptance of cancer drugs
13 and supplies into the program, inspection of cancer drugs
14 and supplies, and dispensing of cancer drugs and supplies
15 to eligible patients; requiring a participant facility
16 that accepts donated drugs and supplies through the
17 program to comply with certain state and federal laws;
18 authorizing a participant facility to charge fees under
19 certain conditions; requiring the Department of Health,
20 upon recommendation of the Board of Pharmacy, to adopt
21 certain rules; providing for the ineligibility of certain
22 persons to receive donated drugs; requiring the department
23 to establish and maintain a participant facility registry;

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24 providing for the contents and availability of the
 25 participant facility registry; providing immunity from
 26 civil and criminal liability for donors or pharmaceutical
 27 manufacturers in certain circumstances; providing that in
 28 the event of conflict between the provisions in s.
 29 499.029, F.S., and provisions in ch. 465 or ch. 499, F.S.,
 30 the provisions in s. 499.029, F.S., shall control;
 31 providing an appropriation; providing an effective date.
 32

33 Be It Enacted by the Legislature of the State of Florida:
 34

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

37 499.029 Cancer Drug Donation Program.--

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

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

44 (3) As used in this section:

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

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

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

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

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

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

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

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

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

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

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

83 (l) "Pharmacist" means a person licensed under chapter
84 465.

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

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

89 (o) "Prescription drug" means a drug as defined in s.
90 465.003 (8).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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

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

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

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