

CHAMBER ACTION

1 The Health Care General Committee 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. 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

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

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. 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.

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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

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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.

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 facility in the program, that exercises reasonable
183 care in donating, accepting, distributing, or dispensing cancer
184 drugs or supplies under the program and the rules adopted under
185 this section shall be immune from civil or criminal liability
186 and 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 or cancer supply manufacturer is not
190 liable for any claim or injury arising from the donation and use
191 of any cancer drug under this section, including, but not
192 limited to, liability for failure to transfer or communicate
193 product or consumer information regarding the donated drug or
194 supply, as well as the expiration date of the donated drug or
195 supply.

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

200 Section 2. This act shall take effect July 1, 2006.