

1 A bill to be entitled
2 An act relating to the Cancer Drug Donation Program;
3 creating s. 381.94, F.S.; providing a short title;
4 creating the Cancer Drug Donation Program; providing a
5 purpose; providing definitions; providing conditions for
6 donation of cancer drugs and supplies to the program;
7 providing conditions for the acceptance of cancer drugs
8 and supplies into the program, inspection of cancer drugs
9 and supplies, and dispensation of cancer drugs and
10 supplies to eligible patients; requiring a physician's
11 office, pharmacy, hospital, hospice, or health care clinic
12 that accepts donated drugs and supplies through the
13 program to comply with certain state and federal laws;
14 authorizing a participating physician's office, pharmacy,
15 hospital, hospice, or health care clinic to charge fees
16 under certain conditions; requiring the Department of
17 Health, upon recommendation of the Board of Pharmacy, to
18 adopt certain rules; providing for the ineligibility of
19 certain persons to receive donated drugs; requiring the
20 department to establish and maintain a participant
21 registry; providing for the contents and availability of
22 the participant registry; providing immunity from civil
23 and criminal liability for donors, program participants,
24 or pharmaceutical manufacturers in certain circumstances;
25 providing an effective date.

26
27 Be It Enacted by the Legislature of the State of Florida:
28

29 Section 1. Section 381.94, Florida Statutes, is created to
 30 read:

31 381.94 Cancer Drug Donation Program.--

32 (1) This act may be cited as the "Cancer Drug Donation
 33 Program Act."

34 (2) There is created a Cancer Drug Donation Program within
 35 the Department of Health for the purpose of authorizing and
 36 facilitating the donation of cancer drugs and supplies to
 37 eligible patients.

38 (3) As used in this section:

39 (a) "Cancer drug" means a prescription drug used to treat
 40 cancer or its side effects or used to treat the side effects of
 41 a prescription drug used to treat cancer or its side effects.

42 (b) "Department" means the Department of Health.

43 (c) "Donor" means a person, health care facility,
 44 hospital, pharmacy, drug manufacturer, medical device
 45 manufacturer or supplier, wholesaler of drugs or supplies, or
 46 any other entity that donates cancer drugs, or supplies needed
 47 to administer such drugs, in accordance with this section.

48 (d) "Eligible patient" means a person who the department
 49 determines is eligible to receive cancer drugs from the program.

50 (e) "Health care facility" means a health care facility
 51 licensed under chapter 395.

52 (f) "Health care clinic" means a health care clinic
 53 licensed under part XIII of chapter 400.

54 (g) "Hospice" means a corporation licensed under part VI
 55 of chapter 400.

56 (h) "Hospital" means a facility as defined in s. 395.002
57 and licensed under chapter 395.

58 (i) "Participant" means a physician's office, pharmacy,
59 hospital, hospice, or health care clinic that has elected to
60 participate in the program and that accepts donated cancer drugs
61 and supplies under the rules adopted by the department for the
62 program.

63 (j) "Pharmacist" means a pharmacist licensed under chapter
64 465.

65 (k) "Pharmacy" means an entity licensed under chapter 465.

66 (l) "Physician's office" means the office of a person
67 licensed to practice medicine under chapter 458 or osteopathic
68 medicine under chapter 459.

69 (m) "Prescribing practitioner" means a physician licensed
70 under chapter 458 or any other medical professional with
71 authority under state law to prescribe cancer medication.

72 (n) "Prescription drug" means a drug as defined in s.
73 465.003(8).

74 (o) "Program" means the Cancer Drug Donation Program
75 created by this section.

76 (p) "Supplies" means any supplies used in the
77 administration of a cancer drug.

78 (4) Any person or entity may donate cancer drugs or
79 supplies to the program. Cancer drugs or supplies may be donated
80 at a physician's office, pharmacy, hospital, hospice, or health
81 care clinic that elects to participate in the program and meets
82 criteria established by the department for such participation.
83 Cancer drugs or supplies may not be donated to a specific cancer

84 patient, and donated drugs or supplies may not be resold by the
85 program.

86 (5) The cancer drug or supplies donated to the program may
87 be prescribed only by a prescribing practitioner for use by an
88 eligible patient and may be dispensed only by a pharmacist.

89 (6)(a) A cancer drug may only be accepted or dispensed
90 under the program if such drug is in its original, unopened,
91 sealed, and tamper-evident unit dose packaging, except that a
92 cancer drug packaged in single unit doses may be accepted and
93 dispensed if the outside packaging is opened but the single-
94 unit-dose packaging is unopened.

95 (b) A cancer drug may not be accepted or dispensed under
96 the program if such drug bears an expiration date that is less
97 than 6 months after the date the drug was donated or if the drug
98 is adulterated or misbranded as determined in paragraph (c).

99 (c) Prior to being dispensed to an eligible patient, the
100 cancer drug or supplies donated under the program shall be
101 inspected by a pharmacist to determine that the drug and
102 supplies are not adulterated or misbranded.

103 (d) A dispenser of donated cancer drugs or supplies may
104 not submit a claim or otherwise seek reimbursement from any
105 public or private third-party payor for donated cancer drugs or
106 supplies dispensed to any patient under the program, and a
107 public or private third-party payor is not required to provide
108 reimbursement to a dispenser for donated cancer drugs or
109 supplies dispensed to any patient under the program.

110 (7)(a) A physician's office, pharmacy, hospital, hospice,
111 or health care clinic that accepts donated cancer drugs or

112 supplies under the program shall comply with all applicable
 113 provisions of state and federal law relating to the storage,
 114 distribution, and dispensing of the donated cancer drugs or
 115 supplies.

116 (b) A physician's office, pharmacy, hospital, hospice, or
 117 health clinic that participates in the program may charge a
 118 nominal handling fee for distributing or dispensing cancer drugs
 119 or supplies under the program. The fee shall be established in
 120 rules adopted by the department.

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

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

128 (b) Standards and procedures for participants that accept,
 129 store, distribute, or dispense donated cancer drugs or supplies.

130 (c) Necessary forms for administration of the program,
 131 including, but not limited to, forms for use by persons or
 132 entities that donate, accept, distribute, or dispense cancer
 133 drugs or supplies under the program.

134 (d) The maximum handling fee that may be charged by a
 135 participant that accepts and distributes or dispenses donated
 136 cancer drugs or supplies.

137 (e) Categories of cancer drugs and supplies that the
 138 program will accept for dispensing.

139 (f) Categories of cancer drugs and supplies that the

140 program will not accept for dispensing and the reason that such
 141 drugs and supplies will not be accepted.

142 (g) Maintenance and distribution of the participant
 143 registry established in subsection (10).

144 (9) A person who is eligible to receive cancer drugs or
 145 supplies under the state Medicaid program or under any other
 146 prescription drug program funded in whole or in part by the
 147 state is ineligible to participate in the program created under
 148 this section.

149 (10) The department shall establish and maintain a
 150 participant registry for the program. The participant registry
 151 shall include the participant's name, address, and telephone
 152 number and shall identify whether the participant is a
 153 physician's office, pharmacy, hospital, hospice, or health care
 154 clinic. The department shall make the participant registry
 155 available to any person or entity wishing to donate cancer drugs
 156 or supplies to the program.

157 (11) Any donor of cancer drugs or supplies, or any
 158 participant in the program, who exercises reasonable care in
 159 donating, accepting, distributing, or dispensing cancer drugs or
 160 supplies under the program and the rules adopted under this
 161 section shall be immune from civil or criminal liability and
 162 from professional disciplinary action of any kind for any
 163 injury, death, or loss to person or property relating to such
 164 activities.

165 (12) A pharmaceutical manufacturer is not liable for any
 166 claim or injury arising from the transfer of any cancer drug
 167 under this section, including, but not limited to, liability for

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168 | failure to transfer or communicate product or consumer
169 | information regarding the transferred drug, as well as the
170 | expiration date of the transferred drug.

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