

By the Committee on Health Care; and Senator Clary

587-2086-06

1 A bill to be entitled
2 An act relating to the Cancer Drug Donation
3 Program; creating s. 381.94, F.S.; providing a
4 short title; creating the Cancer Drug Donation
5 Program; providing a purpose; providing
6 definitions; providing eligibility criteria for
7 cancer patients for the Cancer Drug Donation
8 Program; providing conditions for the donation
9 of cancer drugs and supplies to the program;
10 providing conditions for the acceptance of
11 cancer drugs and supplies into the program,
12 inspection of cancer drugs and supplies, and
13 dispensing of cancer drugs and supplies to
14 eligible patients; requiring a participant
15 facility that accepts donated drugs and
16 supplies through the program to comply with
17 certain state and federal laws; authorizing a
18 participant facility to charge fees under
19 certain conditions; requiring the Department of
20 Health, upon recommendation of the Board of
21 Pharmacy, to adopt certain rules; providing for
22 the ineligibility of certain persons to receive
23 donated drugs; requiring the department to
24 establish and maintain a participant facility
25 registry; providing for the contents and
26 availability of the participant facility
27 registry; providing immunity from civil
28 liability for pharmaceutical manufacturers in
29 certain circumstances; providing that in the
30 event of conflict between the provisions in s.
31 381.94, F.S., and provisions in ch. 465 or ch.

1 499, F.S., the provisions in s. 381.94, F.S.,
2 shall control; providing an appropriation;
3 providing an effective date.

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

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7 Section 1. Section 381.94, Florida Statutes, is
8 created to read:

9 381.94 Cancer Drug Donation Program.--

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

12 (2) There is created a Cancer Drug Donation Program
13 within the Department of Health for the purpose of authorizing
14 and facilitating the donation of cancer drugs and supplies to
15 eligible patients.

16 (3) As used in this section, the term:

17 (a) "Cancer drug" means a prescription drug that has
18 been approved under s. 505 of the federal Food, Drug, and
19 Cosmetic Act and is used to treat cancer or its side effects
20 or is used to treat the side effects of a prescription drug
21 used to treat cancer or its side effects. "Cancer drug" does
22 not include a substance listed in Schedule II, Schedule III,
23 Schedule IV, or Schedule V of s. 893.03.

24 (b) "Closed drug delivery system" means a system in
25 which the actual control of the unit-dose medication package
26 is maintained by the facility rather than by the individual
27 patient.

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

29 (d) "Donor" means a patient or patient representative
30 who donates cancer drugs or supplies needed to administer
31 cancer drugs that have been maintained within a closed drug

1 delivery system; health care facilities, nursing homes,
2 hospices, or hospitals with closed drug delivery systems; or
3 pharmacies, drug manufacturers, medical device manufacturers
4 or suppliers, or wholesalers of drugs or supplies, in
5 accordance with this section. "Donor" includes a physician
6 licensed under chapter 458 or chapter 459 who receives cancer
7 drugs or supplies directly from a drug manufacturer, drug
8 wholesaler, or pharmacy.

9 (e) "Eligible patient" means a person who is a
10 resident of the state, has a diagnosis of cancer from a
11 physician licensed under chapter 458 or chapter 459, holds a
12 valid prescription for a cancer drug, and is not deemed
13 ineligible under subsection (9) to receive a cancer drug.

14 (f) "Health care facility" means a health care
15 facility licensed under chapter 395.

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

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

20 (i) "Hospital" means a facility as defined in s.
21 395.002 and licensed under chapter 395.

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

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

28 (l) "Pharmacist" means a person licensed under chapter
29 465.

30 (m) "Pharmacy" means an entity licensed under chapter
31 465.

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

4 (o) "Prescription drug" means a drug as defined in s.
5 465.003(8).

6 (p) "Program" means the Cancer Drug Donation Program
7 created by this section.

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

10 (4) Any donor may donate cancer drugs or supplies to a
11 participant facility that elects to participate in the program
12 and agrees to comply with requirements of this section and
13 rules established by the department for such participation.
14 Cancer drugs or supplies may not be donated to a specific
15 cancer patient, and donated drugs or supplies may not be
16 resold by the program. A participant facility may provide
17 dispensing and consulting services to individuals who are not
18 patients of the hospital.

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

23 (6)(a) A cancer drug may only be accepted or dispensed
24 under the program if the drug is in its original, unopened,
25 sealed container, or in a tamper-evident unit-dose packaging,
26 except that a cancer drug packaged in single-unit doses may be
27 accepted and dispensed if the outside packaging is opened but
28 the single-unit-dose packaging is unopened with
29 tamper-resistant packaging intact.

30 (b) A cancer drug may not be accepted or dispensed
31 under the program if the drug bears an expiration date that is

1 less than 6 months after the date the drug was donated or if
2 the drug appears to have been tampered with or mislabeled as
3 determined in paragraph (c).

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

9 (d) A dispenser of donated cancer drugs or supplies
10 may not submit a claim or otherwise seek reimbursement from
11 any public or private third-party payor for donated cancer
12 drugs or supplies dispensed to any patient under the program,
13 and a public or private third-party payor is not required to
14 provide reimbursement to a dispenser for donated cancer drugs
15 or supplies dispensed to any patient under the program.

16 (7)(a) A donation of cancer drugs or supplies shall be
17 made only at a participant facility. A participant facility
18 may decline to accept a donation. A participant facility that
19 accepts donated cancer drugs or supplies under the program
20 shall comply with all applicable provisions of state and
21 federal law relating to the storage and dispensing of the
22 donated cancer drugs or supplies.

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

28 (8) The department, upon the recommendation of the
29 Board of Pharmacy, shall adopt rules to carry out the
30 provisions of this section. Initial rules under this section
31 shall be adopted no later than 90 days after the effective

1 date of this act. The rules shall include, but not be limited
2 to:
3 (a) Standards and procedures for participant
4 facilities that accept, store, distribute, or dispense donated
5 cancer drugs or supplies.
6 (b) Necessary forms for administration of the program,
7 including, but not limited to, forms for use by entities that
8 donate, accept, distribute, or dispense cancer drugs or
9 supplies under the program.
10 (c) The maximum handling fee that may be charged by a
11 participant facility that accepts and distributes or dispenses
12 donated cancer drugs or supplies.
13 (d) Categories of cancer drugs and supplies that the
14 program will accept for dispensing; however, the department
15 may exclude any drug based on its therapeutic effectiveness or
16 high potential for abuse or diversion.
17 (e) Maintenance and distribution of the participant
18 facility registry established in subsection (10).
19 (9) A person who is eligible to receive cancer drugs
20 or supplies under the state Medicaid program or under any
21 other prescription drug program funded in whole or in part by
22 the state, by any other prescription drug program funded in
23 whole or in part by the Federal Government, or by any other
24 prescription drug program offered by a third-party insurer,
25 unless benefits have been exhausted, or a certain cancer drug
26 or supply is not covered by the prescription drug program, is
27 ineligible to participate in the program created under this
28 section.
29 (10) The department shall establish and maintain a
30 participant facility registry for the program. The participant
31 facility registry shall include the participant facility's

1 name, address, and telephone number. The department shall make
2 the participant facility registry available on the
3 department's website to any donor wishing to donate cancer
4 drugs or supplies to the program. The department's website
5 shall also contain links to cancer drug manufacturers that
6 offer drug assistance programs or free medication.

7 (11) A pharmaceutical manufacturer is not liable for
8 any claim or injury arising from the transfer of any cancer
9 drug under this section, including, but not limited to,
10 liability for failure to transfer or communicate product or
11 consumer information regarding the transferred drug, as well
12 as the expiration date of the transferred drug.

13 (12) If any conflict exists between the provisions in
14 this section and the provisions in chapter 465 or chapter 499,
15 the provisions in this section shall control the operation of
16 the Cancer Drug Donation Program.

17 Section 2. There is appropriated one full-time
18 equivalent position at the salary rate of \$42,715 and
19 recurring funding from the General Revenue Fund in the sum of
20 \$65,308 for fiscal year 2006-2007, for the purpose of
21 implementing the Cancer Drug Donation Program under s. 381.94,
22 Florida Statutes, as created by this act.

23 Section 3. This act shall take effect July 1, 2006.
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STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
Senate Bill 1310

The bill revises relevant definitions and duties of the Department of Health to implement the Cancer Drug Donation Program. The bill establishes eligibility criteria for patients for the program and provides an appropriation for the Department of Health to implement the program. The bill eliminates an immunity from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to donating, accepting, distributing, or dispensing cancer drugs or supplies under the program.