

Bill No. SB 1310

Barcode 633314

CHAMBER ACTION

Senate

House

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The Committee on Health Care (Fasano) recommended the following amendment:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

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

381.94 Cancer Drug Donation Program.--

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

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

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

(a) "Cancer drug" means a prescription drug that has been approved under s. 505 of the federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug

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1 used to treat cancer or its side effects. "Cancer drug" does
2 not include a substance listed in Schedule II, Schedule III,
3 Schedule IV, or Schedule V of s. 893.03.

4 (b) "Closed drug delivery system" means a system in
5 which the actual control of the unit-dose medication package
6 is maintained by the facility rather than by the individual
7 patient.

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

9 (d) "Donor" means a patient or patient representative
10 who donates cancer drugs or supplies needed to administer
11 cancer drugs that have been maintained within a closed drug
12 delivery system; health care facilities, nursing homes,
13 hospices, or hospitals with closed drug delivery systems; or
14 pharmacies, drug manufacturers, medical device manufacturers
15 or suppliers, or wholesalers of drugs or supplies, in
16 accordance with this section. "Donor" includes a physician
17 licensed under chapter 458 or chapter 459 who receives cancer
18 drugs or supplies directly from a drug manufacturer, drug
19 wholesaler, or pharmacy.

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

23 (f) "Health care facility" means a health care
24 facility licensed under chapter 395.

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

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

29 (i) "Hospital" means a facility as defined in s.
30 395.002 and licensed under chapter 395.

31 (j) "Nursing home" means a facility licensed under

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1 part II of chapter 400.

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

6 (l) "Pharmacist" means a person licensed under chapter
7 465.

8 (m) "Pharmacy" means an entity licensed under chapter
9 465.

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

13 (o) "Prescription drug" means a drug as defined in s.
14 465.003(8).

15 (p) "Program" means the Cancer Drug Donation Program
16 created by this section.

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

19 (4) Any donor may donate cancer drugs or supplies to a
20 participant facility that elects to participate in the program
21 and meets criteria established by the department for such
22 participation. Cancer drugs or supplies may not be donated to
23 a specific cancer patient, and donated drugs or supplies may
24 not be resold by the program. A participant facility may
25 provide dispensing and consulting services to individuals who
26 are not patients of the hospital.

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

31 (6)(a) A cancer drug may only be accepted or dispensed

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1 under the program if the drug is in its original, unopened,
 2 sealed container, or in a tamper-evident unit-dose packaging,
 3 except that a cancer drug packaged in single-unit doses may be
 4 accepted and dispensed if the outside packaging is opened but
 5 the single-unit-dose packaging is unopened with
 6 tamper-resistant packaging intact.

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

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

17 (d) A dispenser of donated cancer drugs or supplies
 18 may not submit a claim or otherwise seek reimbursement from
 19 any public or private third-party payor for donated cancer
 20 drugs or supplies dispensed to any patient under the program,
 21 and a public or private third-party payor is not required to
 22 provide reimbursement to a dispenser for donated cancer drugs
 23 or supplies dispensed to any patient under the program.

24 (7)(a) A donation of cancer drugs or supplies shall be
 25 made only at a participant facility. A participant facility
 26 may decline to accept a donation. A participant facility that
 27 accepts donated cancer drugs or supplies under the program
 28 shall comply with all applicable provisions of state and
 29 federal law relating to the storage and dispensing of the
 30 donated cancer drugs or supplies.

31 (b) A participant facility that voluntarily takes part

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1 in the program may charge a handling fee sufficient to cover
2 the cost of preparation and dispensing of cancer drugs or
3 supplies under the program. The fee shall be established in
4 rules adopted by the department.

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

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

13 (b) Standards and procedures for participant
14 facilities that accept, store, distribute, or dispense donated
15 cancer drugs or supplies.

16 (c) Necessary forms for administration of the program,
17 including, but not limited to, forms for use by entities that
18 donate, accept, distribute, or dispense cancer drugs or
19 supplies under the program.

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

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

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

29 (9) A person who is eligible to receive cancer drugs
30 or supplies under the state Medicaid program or under any
31 other prescription drug program funded in whole or in part by

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1 the state, by any other prescription drug program funded in
 2 whole or in part by the Federal Government, or by any other
 3 prescription drug program offered by a third-party insurer,
 4 unless benefits have been exhausted, or a certain cancer drug
 5 or supply is not covered by the prescription drug program, is
 6 ineligible to participate in the program created under this
 7 section.

8 (10) The department shall establish and maintain a
 9 participant facility registry for the program. The participant
 10 facility registry shall include the participant facility's
 11 name, address, and telephone number. The department shall make
 12 the participant facility registry available on the
 13 department's website to any donor wishing to donate cancer
 14 drugs or supplies to the program. The department's website
 15 shall also contain links to cancer drug manufacturers that
 16 offer drug assistance programs or free medication.

17 (11) Any donor of cancer drugs or supplies, or any
 18 participant in the program, who exercises reasonable care in
 19 donating, accepting, distributing, or dispensing cancer drugs
 20 or supplies under the program and the rules adopted under this
 21 section shall be immune from civil or criminal liability and
 22 from professional disciplinary action of any kind for any
 23 injury, death, or loss to person or property relating to such
 24 activities.

25 (12) A pharmaceutical manufacturer is not liable for
 26 any claim or injury arising from the transfer of any cancer
 27 drug under this section, including, but not limited to,
 28 liability for failure to transfer or communicate product or
 29 consumer information regarding the transferred drug, as well
 30 as the expiration date of the transferred drug.

31 (13) If any conflict exists between the provisions in

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1 this section and the provisions in chapter 465 or chapter 499,
2 the provisions in this section shall control the operation of
3 the Cancer Drug Donation Program.

4 Section 2. There is appropriated one full-time
5 equivalent position at the salary rate of \$42,715 and
6 recurring funding from the General Revenue Fund in the sum of
7 \$65,308 for fiscal year 2006-2007, for the purpose of
8 implementing the Cancer Drug Donation Program under s. 381.94,
9 Florida Statutes, as created by this act.

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

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13 ===== T I T L E A M E N D M E N T =====

14 And the title is amended as follows:

15 Delete everything before the enacting clause

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17 and insert:

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A bill to be entitled

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An act relating to the Cancer Drug Donation
20 Program; creating s. 381.94, F.S.; providing a
21 short title; creating the Cancer Drug Donation
22 Program; providing a purpose; providing
23 definitions; providing conditions for the
24 donation of cancer drugs and supplies to the
25 program; providing conditions for the
26 acceptance of cancer drugs and supplies into
27 the program, inspection of cancer drugs and
28 supplies, and dispensing of cancer drugs and
29 supplies to eligible patients; requiring a
30 participant facility that accepts donated drugs
31 and supplies through the program to comply with

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1 certain state and federal laws; authorizing a
2 participant facility to charge fees under
3 certain conditions; requiring the Department of
4 Health, upon recommendation of the Board of
5 Pharmacy, to adopt certain rules; providing for
6 the ineligibility of certain persons to receive
7 donated drugs; requiring the department to
8 establish and maintain a participant facility
9 registry; providing for the contents and
10 availability of the participant facility
11 registry; providing immunity from civil and
12 criminal liability for donors or pharmaceutical
13 manufacturers in certain circumstances;
14 providing that in the event of conflict between
15 the provisions in s. 381.94, F.S., and
16 provisions in ch. 465 or ch. 499, F.S., the
17 provisions in s. 381.94, F.S., shall control;
18 providing an appropriation; providing an
19 effective date.

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