

Bill No. CS for SB 1310

Barcode 171672

CHAMBER ACTION

Senate

House

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The Committee on Judiciary (Clary) recommended the following amendment:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

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

499.029 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:

(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

Bill No. CS for SB 1310

Barcode 171672

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

Bill No. CS for SB 1310

Barcode 171672

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. Cancer drugs billed to and paid
25 for by Medicaid in long-term care facilities that are eligible
26 for return to stock under federal Medicaid regulations shall
27 be credited to Medicaid and are not eligible for donation
28 under the program. A participant facility may provide
29 dispensing and consulting services to individuals who are not
30 patients of the hospital.

31 (5) The cancer drugs or supplies donated to the

Bill No. CS for SB 1310

Barcode 171672

1 program may be prescribed only by a prescribing practitioner
2 for use by an eligible patient and may be dispensed only by a
3 pharmacist.

4 (6)(a) A cancer drug may only be accepted or dispensed
5 under the program if the drug is in its original, unopened,
6 sealed container, or in a tamper-evident unit-dose packaging,
7 except that a cancer drug packaged in single-unit doses may be
8 accepted and dispensed if the outside packaging is opened but
9 the single-unit-dose packaging is unopened with
10 tamper-resistant packaging intact.

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

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

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

28 (7)(a) A donation of cancer drugs or supplies shall be
29 made only at a participant facility. A participant facility
30 may decline to accept a donation. A participant facility that
31 accepts donated cancer drugs or supplies under the program

Bill No. CS for SB 1310

Barcode 171672

1 shall comply with all applicable provisions of state and
2 federal law relating to the storage and dispensing of the
3 donated cancer drugs or supplies.

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

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

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

17 (b) Standards and procedures for participant
18 facilities that accept, store, distribute, or dispense donated
19 cancer drugs or supplies.

20 (c) Necessary forms for administration of the program,
21 including, but not limited to, forms for use by entities that
22 donate, accept, distribute, or dispense cancer drugs or
23 supplies under the program.

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

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

31 (f) Maintenance and distribution of the participant

Bill No. CS for SB 1310

Barcode 171672

1 facility registry established in subsection (10).

2 (9) A person who is eligible to receive cancer drugs
3 or supplies under the state Medicaid program or under any
4 other prescription drug program funded in whole or in part by
5 the state, by any other prescription drug program funded in
6 whole or in part by the Federal Government, or by any other
7 prescription drug program offered by a third-party insurer,
8 unless benefits have been exhausted, or a certain cancer drug
9 or supply is not covered by the prescription drug program, is
10 ineligible to participate in the program created under this
11 section.

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

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

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

Bill No. CS for SB 1310

Barcode 171672

1 liability for failure to transfer or communicate product or
2 consumer information regarding the transferred drug, as well
3 as the expiration date of the transferred drug.

4 (13) If any conflict exists between the provisions in
5 this section and the provisions in this chapter or chapter
6 465, the provisions in this section shall control the
7 operation of the Cancer Drug Donation Program.

8 Section 2. There is hereby appropriated one full-time
9 equivalent position at salary rate 42,715 and recurring
10 funding from the Florida Drug, Device, and Cosmetic Trust Fund
11 pursuant to s. 499.057, Florida Statutes, in the sum of
12 \$65,308 for fiscal year 2006-2007, for the purpose of
13 implementing the Cancer Drug Donation Program under s.
14 499.029, Florida Statutes, as created by this act.

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

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

19 And the title is amended as follows:

20 Delete everything before the enacting clause

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22 and insert:

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A bill to be entitled

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An act relating to the Cancer Drug Donation

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Program; creating s. 499.029, F.S.; providing a

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short title; creating the Cancer Drug Donation

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Program; providing a purpose; providing

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definitions; providing conditions for the

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donation of cancer drugs and supplies to the

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program; providing conditions for the

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acceptance of cancer drugs and supplies into

Bill No. CS for SB 1310

Barcode 171672

1 the program, inspection of cancer drugs and
2 supplies, and dispensing of cancer drugs and
3 supplies to eligible patients; requiring a
4 participant facility that accepts donated drugs
5 and supplies through the program to comply with
6 certain state and federal laws; authorizing a
7 participant facility to charge fees under
8 certain conditions; requiring the Department of
9 Health, upon recommendation of the Board of
10 Pharmacy, to adopt certain rules; providing for
11 the ineligibility of certain persons to receive
12 donated drugs; requiring the department to
13 establish and maintain a participant facility
14 registry; providing for the contents and
15 availability of the participant facility
16 registry; providing immunity from civil and
17 criminal liability for donors or pharmaceutical
18 manufacturers in certain circumstances;
19 providing that in the event of conflict between
20 the provisions in s. 499.029, F.S., and
21 provisions in ch. 465 or ch. 499, F.S., the
22 provisions in s. 499.029, F.S., shall control;
23 providing an appropriation; providing an
24 effective date.

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