

By Senator Clary

4-736-06

See HB 371

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 conditions for donation
7 of cancer drugs and supplies to the program;
8 providing conditions for the acceptance of
9 cancer drugs and supplies into the program,
10 inspection of cancer drugs and supplies, and
11 dispensation of cancer drugs and supplies to
12 eligible patients; requiring a physician's
13 office, pharmacy, hospital, hospice, or health
14 care clinic that accepts donated drugs and
15 supplies through the program to comply with
16 certain state and federal laws; authorizing a
17 participating physician's office, pharmacy,
18 hospital, hospice, or health care clinic to
19 charge fees under certain conditions; requiring
20 the Department of Health, upon recommendation
21 of the Board of Pharmacy, to adopt certain
22 rules; providing for the ineligibility of
23 certain persons to receive donated drugs;
24 requiring the department to establish and
25 maintain a participant registry; providing for
26 the contents and availability of the
27 participant registry; providing immunity from
28 civil and criminal liability for donors,
29 program participants, or pharmaceutical
30 manufacturers in certain circumstances;
31 providing an effective date.

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

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

5 381.94 Cancer Drug Donation Program.--

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

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

12 (3) As used in this section:

13 (a) "Cancer drug" means a prescription drug used to
14 treat cancer or its side effects or used to treat the side
15 effects of a prescription drug used to treat cancer or its
16 side effects.

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

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

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

26 (e) "Health care facility" means a health care
27 facility licensed under chapter 395.

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

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

1 (h) "Hospital" means a facility as defined in s.
2 395.002 and licensed under chapter 395.

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

8 (j) "Pharmacist" means a pharmacist licensed under
9 chapter 465.

10 (k) "Pharmacy" means an entity licensed under chapter
11 465.

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

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

18 (n) "Prescription drug" means a drug as defined in s.
19 465.003(8).

20 (o) "Program" means the Cancer Drug Donation Program
21 created by this section.

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

24 (4) Any person or entity may donate cancer drugs or
25 supplies to the program. Cancer drugs or supplies may be
26 donated at a physician's office, pharmacy, hospital, hospice,
27 or health care clinic that elects to participate in the
28 program and meets criteria established by the department for
29 such participation. Cancer drugs or supplies may not be
30 donated to a specific cancer patient, and donated drugs or
31 supplies may not be resold by the program.

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

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

11 (b) A cancer drug may not be accepted or dispensed
12 under the program if such drug bears an expiration date that
13 is less than 6 months after the date the drug was donated or
14 if the drug is adulterated or misbranded as determined in
15 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 are not adulterated or misbranded.

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

27 (7)(a) A physician's office, pharmacy, hospital,
28 hospice, or health care clinic that accepts donated cancer
29 drugs or supplies under the program shall comply with all
30 applicable provisions of state and federal law relating to the
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1 storage, distribution, and dispensing of the donated cancer
2 drugs or supplies.

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

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

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

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

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

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

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

28 (f) Categories of cancer drugs and supplies that the
29 program will not accept for dispensing and the reason that
30 such drugs and supplies will not be accepted.

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1 (9) Maintenance and distribution of the participant
2 registry established in subsection (10).

3 (9) A person who is eligible to receive cancer drugs
4 or supplies under the state Medicaid program or under any
5 other prescription drug program funded in whole or in part by
6 the state is ineligible to participate in the program created
7 under this section.

8 (10) The department shall establish and maintain a
9 participant registry for the program. The participant registry
10 shall include the participant's name, address, and telephone
11 number and shall identify whether the participant is a
12 physician's office, pharmacy, hospital, hospice, or health
13 care clinic. The department shall make the participant
14 registry available to any person or entity wishing to donate
15 cancer drugs or supplies to the program.

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

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

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