

By: Nelson

S.B. No. 39

A BILL TO BE ENTITLED

AN ACT

relating to a cancer drug donation program.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Chapter 431, Health and Safety Code, is amended by adding Subchapter O to read as follows:

SUBCHAPTER O. CANCER DRUG DONATION PROGRAM

Sec. 431.451. DEFINITIONS. In this subchapter:

(1) "Cancer drug" means a prescription drug used to treat:

(A) cancer or its side effects; or

(B) the side effects of a prescription drug used to treat cancer or its side effects.

(2) "Department" means the Department of State Health Services.

(3) "Health care facility" means:

(A) a general or special hospital as defined by Chapter 241;

(B) an ambulatory surgical center licensed under Chapter 243;

(C) an institution licensed under Chapter 242;  
or

(D) any other facility, including an outpatient clinic, that provides diagnosis or treatment services to patients with cancer.

1           (4) "Participant" means a physician's office,  
2 pharmacy, or health care facility that has elected to participate  
3 in the program and that accepts donated cancer drugs and supplies  
4 under the rules adopted by the department for the program.

5           (5) "Pharmacy" means an entity licensed under Chapter  
6 560, Occupations Code.

7           (6) "Physician's office" means the office of a person  
8 licensed to practice medicine in this state or another state of the  
9 United States.

10          (7) "Practitioner" has the meaning assigned by Section  
11 551.003, Occupations Code.

12          (8) "Prescription drug" has the meaning assigned by  
13 Section 551.003, Occupations Code.

14          (9) "Program" means the cancer drug donation program  
15 created under this subchapter.

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

18          Sec. 431.452. DONATION TO PROGRAM. (a) A person may donate  
19 a cancer drug or supplies to the program at a physician's office,  
20 pharmacy, or health care facility that elects to participate in the  
21 program and meets criteria established by the department for  
22 participation.

23          (b) A person may not donate, through the program, a cancer  
24 drug or supplies for a specific individual.

25          (c) A participant may not resell a cancer drug or supplies  
26 donated to the program.

27          Sec. 431.453. DISTRIBUTION. A cancer drug or supplies

1 distributed to an eligible individual under the program must:

2 (1) be prescribed by a practitioner for use by an  
3 eligible individual; and

4 (2) be dispensed by a pharmacist.

5 Sec. 431.454. REQUIREMENTS FOR DONATED DRUGS AND SUPPLIES.

6 (a) Except as provided by this subsection, a cancer drug or  
7 supplies may only be accepted or dispensed under the program if the  
8 drug is in its original, unopened, sealed, and tamper-evident  
9 unit-dose packaging. A cancer drug packaged in single unit doses  
10 may be accepted and dispensed if the outside packaging is opened but  
11 the single-unit-dose packaging is unopened.

12 (b) A cancer drug may not be accepted or dispensed under the  
13 program if the drug:

14 (1) bears an expiration date that is earlier than six  
15 months after the date the drug was donated; or

16 (2) is adulterated or misbranded as determined under  
17 Subsection (c).

18 (c) Before being dispensed to an eligible individual, a  
19 cancer drug or supplies donated under the program must be inspected  
20 by a pharmacist to determine that the drug or supplies are not  
21 adulterated or misbranded.

22 (d) A dispenser of donated products may not submit a claim  
23 or otherwise seek reimbursement from any public or private third  
24 party payer for donated drugs dispensed to an eligible individual  
25 under the program, and a public or private third party payer is not  
26 required to provide reimbursement for donated drugs dispensed to an  
27 individual through the program.

1       Sec. 431.455. STORAGE, DISTRIBUTION, AND DISPENSING; FEE.

2       (a) A participant shall comply with all applicable provisions of  
3 state and federal law relating to the storage, distribution, and  
4 dispensing of donated cancer drugs.

5       (b) A participant may charge a nominal handling fee for  
6 distributing or dispensing cancer drugs or supplies under the  
7 program.

8       Sec. 431.456. ELIGIBILITY REQUIREMENTS AND RESTRICTIONS.

9       (a) To be eligible to receive cancer drugs or supplies under the  
10 program, an individual must be uninsured or underinsured, as  
11 determined by department rule.

12       (b) An individual who is eligible to receive drugs or  
13 supplies under the medical assistance program under Chapter 32,  
14 Human Resources Code, or under any other prescription drug program  
15 funded wholly or partly by the state is not eligible to receive  
16 cancer drugs or supplies under the program.

17       Sec. 431.457. RULES. The department, on the recommendation  
18 of the Texas State Board of Pharmacy, shall adopt rules to carry out  
19 this subchapter. Rules adopted under this section must address:

20               (1) eligibility criteria, including a method to  
21 determine priority of recipients under the program;

22               (2) standards and procedures for participants that  
23 accept, store, distribute, or dispense donated cancer drugs or  
24 supplies;

25               (3) necessary forms for administration of the program,  
26 including forms for use by persons who donate, accept, distribute,  
27 or dispense cancer drugs or supplies under the program;

1           (4) the maximum handling fee that may be charged by a  
2 participant under Section 431.455(b);

3           (5) categories of cancer drugs and supplies that the  
4 program will accept for dispensing;

5           (6) categories of cancer drugs and supplies that the  
6 program will not accept for dispensing and the reason that such  
7 drugs and supplies will not be accepted; and

8           (7) maintenance and distribution of the participant  
9 registry established under Section 431.458.

10           Sec. 431.458. PARTICIPANT REGISTRY. The department shall  
11 establish and maintain a participant registry for the program. The  
12 department shall make the participant registry available to any  
13 person wishing to donate cancer drugs or supplies to the program.  
14 The participant registry shall:

15           (1) include the participant's name, address, and  
16 telephone number; and

17           (2) identify whether the participant is a physician's  
18 office, a pharmacy, or a health care facility.

19           Sec. 431.459. LIABILITY. (a) A donor of a cancer drug or  
20 supplies, or a participant in the program who exercises reasonable  
21 care in donating, accepting, distributing, or dispensing cancer  
22 drugs or supplies under the program, is not criminally liable, is  
23 not civilly liable for damages other than economic damages, and is  
24 not subject to professional disciplinary action for bodily injury,  
25 death, or property damage that arises from those activities.

26           (b) A pharmaceutical manufacturer is not liable for  
27 damages, other than economic damages, for bodily injury, death, or

1 property damage that arise from the transfer of a prescription drug  
2 under this subchapter, including liability for failure to transfer  
3 or communicate product or consumer information regarding the  
4 transferred drug, including the expiration date of the transferred  
5 drug.

6 SECTION 2. The Department of State Health Services shall  
7 adopt initial rules for Subchapter O, Chapter 431, Health and  
8 Safety Code, as added by this Act, not later than December 1, 2007.

9 SECTION 3. (a) Section 431.459, Health and Safety Code, as  
10 added by this Act, applies only to a cause of action that accrues on  
11 or after the effective date of this Act. An action that accrued  
12 before the effective date of this Act is governed by the law  
13 applicable to the action immediately before the effective date of  
14 this Act, and that law is continued in effect for that purpose.

15 (b) Section 431.459, Health and Safety Code, as added by  
16 this Act, is an exercise of authority under Section 66(c), Article  
17 III, Texas Constitution, and takes effect only if this Act receives  
18 a vote of three-fifths of all the members elected to each house, as  
19 provided by Section 66(e) of that article.

20 SECTION 4. This Act takes effect September 1, 2007.