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**SUBSTITUTE SENATE BILL 6049**

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**State of Washington**

**62nd Legislature**

**2012 Regular Session**

**By** Senate Health & Long-Term Care (originally sponsored by Senators Kastama and Shin)

READ FIRST TIME 01/24/12.

1       AN ACT Relating to requiring the department of health to establish  
2 a cancer drug repository program; and adding a new chapter to Title 70  
3 RCW.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5       NEW SECTION.   **Sec. 1.** The definitions in this section apply  
6 throughout this chapter unless the context clearly requires otherwise.

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

8       (a) Cancer or its side effects; or

9       (b) The side effects of a prescription drug used to treat cancer or  
10 its side effects.

11       (2) "Department" means the department of health.

12       (3) "Donor" means a person, practitioner, health care facility, or  
13 an individual or entity licensed under chapter 18.64 RCW.

14       (4) "Health care facility" means a hospital, medical clinic,  
15 nursing home, practitioner office, or pharmacy.

16       (5) "Hospital" has the meaning provided in RCW 70.41.020.

17       (6) "Pharmacy" means every place properly licensed by the board of  
18 pharmacy where the practice of pharmacy is conducted.

1 (7) "Practitioner" means a health care practitioner defined in RCW  
2 69.41.010 who is authorized to prescribe cancer drugs.

3 (8) "Program" means the cancer drug repository program.

4 (9) "Single-unit dose packaging" means a single-unit container for  
5 articles intended for administration as a single dose, direct from the  
6 container.

7 (10) "Tamper-evident unit dose packaging" means a container within  
8 which a drug is sealed so that the contents cannot be opened without  
9 obvious destruction of the seal.

10 NEW SECTION. **Sec. 2.** (1) The department must establish a cancer  
11 drug repository program for accepting cancer drugs from donors and  
12 dispensing donated cancer drugs to Washington residents holding a valid  
13 prescription for such drugs. Participation in the program is  
14 voluntary.

15 (2) The department, in consultation with the board of pharmacy,  
16 must adopt rules to carry out this chapter, including:

17 (a) Eligibility criteria and other standards and procedures for  
18 participating practitioners or pharmacies that accept and distribute or  
19 dispense donated cancer drugs. Standards and procedures must require  
20 the inspection of donated cancer drugs by the practitioner or  
21 pharmacist to determine that the packaging is tamper-evident and that  
22 the donated prescription drugs are unadulterated, not misbranded and  
23 safe, and suitable for redistribution, including determining that:

24 (i) The cancer drug is in its original sealed and tamper-evident  
25 unit dose packaging; and

26 (ii) In the case of opened packages, that the single-unit dose  
27 packaging remains intact;

28 (b) Necessary forms for administration of the program, including  
29 forms to be completed by donors, and forms for use by practitioners and  
30 pharmacies that accept, distribute, or dispense cancer drugs under the  
31 program. A person receiving cancer drugs under the program must be  
32 provided a form disclosing that the drug was donated;

33 (c) The maximum handling fee that may be charged by participating  
34 practitioners or pharmacies for distributing or dispensing cancer drugs  
35 under the program. Handling fees must be paid by the recipient of the  
36 cancer drug and may not be charged, in whole or in part, to any third  
37 party;

1 (d) Categories of cancer drugs that the program will and will not  
2 accept for dispensing; and

3 (e) Maintenance and distribution of the participating practitioner  
4 or pharmacy registry under section 6 of this act.

5 NEW SECTION. **Sec. 3.** (1) A cancer drug may only be donated to,  
6 accepted by, or dispensed under the program if it is in unopened,  
7 sealed, and tamper-evident unit dose packaging or in single-unit dose  
8 packaging if the outside packaging is opened but the single-unit dose  
9 packaging is intact.

10 (2) A cancer drug may not be donated to, accepted by, or dispensed  
11 under the program if it:

12 (a) Is expired; or

13 (b) Is adulterated or misbranded.

14 NEW SECTION. **Sec. 4.** (1) Participating practitioners or  
15 pharmacies must comply with state and federal laws on storage,  
16 distribution, and dispensing of cancer drugs received under the  
17 program. Participating practitioners or pharmacies must comply with  
18 department rules on inspecting donated prescription drugs. Cancer  
19 drugs received under the program may only be dispensed pursuant to a  
20 prescription issued by a prescribing practitioner or may be distributed  
21 to another participating practitioner or pharmacy for dispensing.

22 (2) Participating practitioners or pharmacies may charge a handling  
23 fee, in accordance with department rule, for distributing or dispensing  
24 cancer drugs under the program. Cancer drugs donated under the program  
25 may not be resold or charged, in whole or in part, to any third party.

26 NEW SECTION. **Sec. 5.** (1) Any person or entity that donates,  
27 accepts, or dispenses prescription drugs under this section shall not,  
28 in the absence of negligence, be subject to any of the following for  
29 matters related to donating, accepting, or dispensing such prescription  
30 drugs: Criminal prosecution, liability in tort or other civil action  
31 for injury, death, or loss to person or property, or professional  
32 disciplinary action.

33 A drug manufacturer shall not, in the absence of negligence, be  
34 subject to criminal prosecution or liability in tort or other civil  
35 action for injury, death, or loss to person or property for matters

1 related to the donation, acceptance, or dispensing of a drug  
2 manufactured by the drug manufacturer that is donated by any person  
3 under the program, including liability for failure to transfer or  
4 communicate product or consumer information or the expiration date of  
5 the donated drug.

6 (2) The donation of a cancer drug by a cancer drug manufacturer  
7 does not absolve the manufacturer of any criminal or civil liability  
8 that would have existed but for the donation, nor shall such donation  
9 increase the liability of such cancer drug manufacturer that would have  
10 existed but for the donation.

11 NEW SECTION. **Sec. 6.** The department must establish and maintain  
12 a participating practitioner or pharmacy registry for the program. The  
13 participating practitioner or pharmacy registry must include the  
14 participating practitioner's or pharmacy's name, address, and telephone  
15 number. The participating practitioner or pharmacy registry must be  
16 available to any person or entity wishing to donate cancer drugs to the  
17 program.

18 NEW SECTION. **Sec. 7.** Sections 1 through 6 of this act constitute  
19 a new chapter in Title 70 RCW.

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