

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2007

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SENATE DRS55700-LN-304 (3/11)

Short Title: Cancer Drug and Medical Device Repository. (Public)

Sponsors: Senator Purcell.

Referred to:

A BILL TO BE ENTITLED

AN ACT TO ESTABLISH THE CANCER DRUG, SUPPLIES, AND MEDICAL
DEVICE REPOSITORY PROGRAM IN THE DEPARTMENT OF HEALTH AND
HUMAN SERVICES, DIVISION OF PUBLIC HEALTH.

The General Assembly of North Carolina enacts:

SECTION 1. Part 1 of Article 7 of Chapter 130A of the General Statutes is amended by adding the following new sections to read:

"§ 130A-216. Cancer drug and medical device repository program established.

(a) As used in this section unless the context clearly requires otherwise, the following definitions apply:

- (1) Cancer drug. – A prescription drug that is used to treat cancer or the side effects of cancer.
- (2) Dispense. – To deliver a cancer drug to an eligible patient pursuant to the lawful order of a practitioner, including the administering, prescribing, packaging, labeling, or compounding necessary to prepare the cancer drug for that delivery.
- (3) Eligible patient. – An uninsured or underinsured cancer patient who meets the eligibility criteria established by the Department, health care facility, or pharmacy.
- (4) Health care facility. – An institution providing health care services, including a hospital, clinic, or other inpatient center, outpatient facility, or diagnostic or treatment center that is licensed by the State.
- (5) Pharmacist. – A person licensed by the North Carolina Pharmacy Board to practice pharmacy.
- (6) Pharmaceutical care. – The provision of drug therapy and other patient-care services related to drug therapy intended to achieve definite outcomes that improve a patient's quality of life, including

1 identifying potential and actual drug-related problems, resolving actual
2 drug-related problems, and preventing potential drug-related problems.

3 (7) Pharmacy. – A licensed place of business where drugs are
4 compounded or dispensed and pharmaceutical care is provided.

5 (8) Practitioner or health care practitioner. – A physician or other provider
6 of health services licensed or otherwise permitted to distribute,
7 dispense, or administer cancer drugs or medical devices.

8 (9) Supplies. – Supplies associated with or necessary for the
9 administration of a cancer drug.

10 (b) The Department shall establish and administer a cancer drug and medical
11 device repository program (program). The purpose of the program is to allow a cancer
12 patient or the patient's family to donate unused cancer drugs, supplies to administer the
13 cancer drug, and medical devices to uninsured and underinsured cancer patients in this
14 State. The unused cancer drugs, supplies, and medical devices shall be donated to a
15 health care facility or pharmacy that elects to participate in the program. A health care
16 facility or pharmacy that receives a donated unused cancer drug, supplies, or medical
17 device under the program may distribute the cancer drug, supplies, or medical device to
18 another eligible health care facility or pharmacy for use under the program.

19 (c) A pharmacist may accept and dispense cancer drugs, supplies, and medical
20 devices donated to the program to eligible patients if all of the following requirements
21 are met:

22 (1) The cancer drug, supplies, or medical device is in its original,
23 unopened, sealed, and tamper-evident packaging or, if packaged in
24 single-unit doses, the single-unit dose packaging is unopened.

25 (2) The pharmacist has determined that the cancer drug, supplies, or
26 medical device is safe for redistribution.

27 (3) The cancer drug bears an expiration date that is later than six months
28 after the date that the drug was donated.

29 (4) The cancer drug, supplies, or medical device is not adulterated or
30 misbranded, as determined by a pharmacist.

31 (5) The cancer drug, supplies, or medical device is prescribed by a health
32 care practitioner for use by an eligible patient and is dispensed by a
33 pharmacist.

34 (d) A cancer drug, supplies, or a medical device donated to the program shall not
35 be resold. A health care facility or pharmacy may charge an eligible patient a handling
36 fee to receive a donated cancer drug, supplies, or medical device, which shall not
37 exceed the amount specified in rules adopted by the North Carolina Board of Pharmacy.

38 (e) Nothing in this section requires a health care facility or pharmacy to
39 participate in the program.

40 (f) The Department, in consultation with the North Carolina Board of Pharmacy,
41 shall establish eligibility criteria for individuals to receive donated cancer drugs,
42 supplies, or medical devices. Dispensing shall be prioritized to cancer patients who are
43 uninsured or underinsured. Dispensing to other cancer patients shall be permitted if an
44 uninsured or underinsured cancer patient is not available.

1 (g) The Department, in consultation with the North Carolina Board of Pharmacy,
2 shall adopt rules necessary for the implementation of the program. Rules adopted by the
3 Department shall provide for the following:

4 (1) Requirements for health care facilities and pharmacies to accept and
5 dispense donated cancer drugs, supplies, and medical devices pursuant
6 to the program, including eligibility criteria and standards and
7 procedures for a health care facility or pharmacy to accept, and safely
8 store and dispense donated cancer drugs and medical devices.

9 (2) The amount of the maximum handling fee that a health care facility or
10 pharmacy may charge for distributing or dispensing donated cancer
11 drugs, supplies, or medical devices.

12 (3) A list of cancer drugs, supplies to administer cancer drugs, and
13 medical devices, arranged either by category or by individual drug,
14 supply or medical device, that the program will accept for dispensing.

15 (h) Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer is
16 not subject to criminal or civil liability for injury, death, or loss to a person or property
17 for matters related to the donation, acceptance, or dispensing of a cancer drug or
18 medical device manufactured by the manufacturer that is donated by any person under
19 the program, including liability for failure to transfer or communicate product or
20 consumer information or the expiration date of the donated cancer drug or medical
21 device.

22 (i) The following individuals or entities are immune from civil liability for an act
23 or omission that causes injury to or the death of an individual to whom the cancer drug,
24 supplies, or medical device that is dispensed under the program and no disciplinary
25 action may be taken against a pharmacist or practitioner as long as the drug, supply, or
26 device is donated in accordance with the requirements of this section.

27 (1) A pharmacy or medical facility participating in the program.

28 (2) A pharmacist dispensing a drug, supply, or medical device pursuant to
29 the program.

30 (3) A practitioner administering a drug or supply pursuant to the program.

31 (4) The donor of a cancer drug, supply, or medical device donated
32 pursuant to the program."

33 **SECTION 2.** Article 4A of Chapter 90 of the General Statutes is amended
34 by adding the following new section to read:

35 **"§ 90-85.42. Pharmacies may elect to participate in the cancer drug and medical**
36 **device repository program.**

37 A pharmacy operating in this State may elect to participate in the cancer drug and
38 medical device repository program established under G.S. 130A-216.

39 **SECTION 3.** There is appropriated from the General Fund to the
40 Department of Health and Human Services, Division of Public Health, the sum of one
41 hundred thousand dollars (\$100,000) for the 2008-2009 fiscal year for the
42 implementation of this act.

43 **SECTION 4.** Section 3 of this act becomes effective July 1, 2008. The
44 remainder of this act is effective when it becomes law.