

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2009

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HOUSE BILL 1296
Committee Substitute Favorable 5/13/09

Short Title: Est. Drug And Medical Device Repository/BoP.

(Public)

Sponsors:

Referred to:

April 9, 2009

1 A BILL TO BE ENTITLED
2 AN ACT TO ESTABLISH THE DRUG, SUPPLIES, AND MEDICAL DEVICE
3 REPOSITORY PROGRAM IN THE NORTH CAROLINA BOARD OF PHARMACY.

4 The General Assembly of North Carolina enacts:

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

7 "**§ 130A-216. Drug and medical device repository program established.**

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

- 10 (1) Board. – The North Carolina Board of Pharmacy.
- 11 (2) Drug. – A human drug required by federal law or regulation to be dispensed
12 only by a prescription, including finished dosage forms and active
13 ingredients subject to 21 U.S.C. § 353(b).
- 14 (3) Dispense. – To deliver a drug to an eligible patient pursuant to the lawful
15 order of a practitioner, including the administering, prescribing, packaging,
16 labeling, or compounding necessary to prepare the drug for that delivery.
- 17 (4) Eligible patient. – An uninsured or underinsured patient who meets the
18 eligibility criteria established by the Department, health care facility, or
19 pharmacy.
- 20 (5) Free clinic facility. – A private, nonprofit, community-based organization
21 that (i) provides health care services at little or no charge to low-income,
22 uninsured, and underinsured persons through the use of volunteer health care
23 professionals and partnerships with other health providers and (ii) is licensed
24 by the State.
- 25 (6) Pharmacist. – A person licensed by the North Carolina Board of Pharmacy
26 to practice pharmacy.
- 27 (7) Pharmaceutical care. – The provision of drug therapy and other patient-care
28 services related to drug therapy intended to achieve definite outcomes that
29 improve a patient's quality of life, including identifying potential and actual
30 drug-related problems, resolving actual drug-related problems, and
31 preventing potential drug-related problems.
- 32 (8) Pharmacy. – A licensed place of business where drugs are compounded or
33 dispensed and pharmaceutical care is provided.
- 34 (9) Practitioner or health care practitioner. – A physician or other provider of
35 health services licensed or otherwise permitted to distribute, dispense, or
36 administer drugs or medical devices.



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1 (10) Supplies. – Supplies associated with or necessary for the administration of a
2 drug.

3 (b) The Board shall establish and administer a drug and medical device repository
4 program (program). The purpose of the program is to allow a patient or the patient's family to
5 donate unused drugs, supplies to administer the drug, and medical devices to uninsured and
6 underinsured patients in this State. The unused drugs, supplies, and medical devices shall be
7 donated to a free clinic facility or pharmacy that elects to participate in the program. A free
8 clinic facility that receives a donated unused drug, supplies, or medical device under the
9 program may distribute the drug, supplies, or medical device to another free clinic facility or
10 pharmacy for use under the program.

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

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

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

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

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

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

24 (d) A drug, supplies, or a medical device donated to the program shall not be resold. A
25 free clinic facility or pharmacy may charge an eligible patient a handling fee to receive a
26 donated drug, supplies, or medical device, which shall not exceed the amount specified in rules
27 adopted by the Board.

28 (e) Nothing in this section requires a free clinic facility or pharmacy to participate in the
29 program.

30 (f) The Board shall establish eligibility criteria for individuals to receive donated drugs,
31 supplies, or medical devices. Dispensing shall be prioritized to patients who are uninsured or
32 underinsured. Dispensing to other patients shall be permitted if an uninsured or underinsured
33 patient is not available.

34 (g) The Board shall adopt rules necessary for the implementation of the program. Rules
35 adopted by the Board shall provide for the following:

36 (1) Requirements for free clinic facilities and pharmacies to accept and dispense
37 donated drugs, supplies, and medical devices pursuant to the program,
38 including eligibility criteria and standards and procedures for a free clinic
39 facility or pharmacy to accept, and safely store and dispense donated drugs
40 and medical devices.

41 (2) The amount of the maximum handling fee that a free clinic facility or
42 pharmacy may charge for distributing or dispensing donated drugs, supplies,
43 or medical devices.

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

47 (h) Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer is not
48 subject to criminal or civil liability for injury, death, or loss to a person or property for matters
49 related to the donation, acceptance, or dispensing of a drug or medical device manufactured by
50 the manufacturer that is donated by any person under the program, including liability for failure

1 to transfer or communicate product or consumer information or the expiration date of the
2 donated drug or medical device.

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

8 (1) A pharmacy or free clinic facility participating in the program.

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

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

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

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

16 "**§ 90-85.42. Pharmacies may elect to participate in the drug and medical device**
17 **repository program.**

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

20 **SECTION 3.** This act is effective when it becomes law.