

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2009

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HOUSE BILL 1296  
Committee Substitute Favorable 5/13/09  
PROPOSED SENATE COMMITTEE SUBSTITUTE H1296-PCS50767-RD-72

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. Effective October 1, 2009, Article 4A of Chapter 90 of the General  
6 Statutes is amended by designating G.S. 90-85.2 through G.S. 90-85.43 as "Part 1. North  
7 Carolina Pharmacy Practice Act."

8 SECTION 2. Effective October 1, 2009, Article 4A of Chapter 90 of the General  
9 Statutes, as amended by Section 1 of this act, is amended by adding the following new Part to  
10 read:

11 "Part 2. Drug, Supplies, and Medical Device Repository Program.

12 "§ 90-85.44. Drug, Supplies, and Medical Device Repository Program established.

13 (a) Definitions. – As used in this section unless the context clearly requires otherwise,  
14 the following definitions apply:

15 (1) Board. – As defined in G.S. 90-85.3.

16 (2) Dispense. – As defined in G.S. 90-85.3.

17 (3) Drug. – As defined in G.S. 90-85.3.

18 (4) Eligible donor. – The following are eligible donors under the Program:

19 a. A patient or the patient's family member.

20 b. A manufacturer, wholesaler, or supplier of drugs, supplies, or  
21 medical devices.

22 c. A pharmacy, free clinic, hospital, or a hospice care program.

23 (5) Eligible patient. – An uninsured or underinsured patient who meets the  
24 eligibility criteria established by the Board, free clinic, or pharmacy.

25 (6) Free clinic. – A private, nonprofit, community-based organization that  
26 provides health care services at little or no charge to low-income, uninsured,  
27 and underinsured persons through the use of volunteer health care  
28 professionals.

29 (7) Medical device. – A device as defined in G.S. 90-85.3(e).

30 (8) Pharmacist. – As defined in G.S. 90-85.3.

31 (9) Pharmacy. – As defined in G.S. 90-85.3.



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1           (10) Practitioner. – A physician or other provider of health services licensed or  
2           otherwise permitted to distribute, dispense, or administer drugs, supplies, or  
3           medical devices.

4           (11) Program. – The Drug, Supplies, and Medical Device Repository Program  
5           established under this act.

6           (12) Supplies. – Supplies associated with or necessary for the administration of a  
7           drug.

8           (b) Program Purpose. – The Board shall establish and administer the Program. The  
9           purpose of the Program is to allow an eligible donor to donate unused drugs, supplies, and  
10           medical devices to uninsured and underinsured patients in this State. The unused drugs,  
11           supplies, and medical devices shall be donated to a free clinic or pharmacy that elects to  
12           participate in the Program. A free clinic that receives a donated unused drug, supplies, or  
13           medical device under the Program may distribute the drug, supplies, or medical device to  
14           another free clinic or pharmacy for use under the Program.

15           (c) Requirements of Participating Pharmacists or Free Clinics. – A pharmacist may  
16           accept and dispense drugs, supplies, and medical devices donated to the Program to eligible  
17           patients if all of the following requirements are met:

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

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

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

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

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

29           (d) Fee. – A participating pharmacist or free clinic shall not resell a drug, supplies, or a  
30           medical device donated to the Program. A pharmacist or free clinic may charge an eligible  
31           patient a handling fee to receive a donated drug, supplies, or medical device, which shall not  
32           exceed the amount specified in rules adopted by the Board.

33           (e) Program Participation Voluntary. – Nothing in this section requires a free clinic or  
34           pharmacy to participate in the Program.

35           (f) Eligible Patient. – The Board shall establish eligibility criteria for individuals to  
36           receive donated drugs, supplies, or medical devices. Board eligibility criteria shall provide that  
37           individuals meeting free clinic or pharmacy eligibility criteria are eligible patients. Dispensing  
38           shall be prioritized to patients who are uninsured or underinsured. Dispensing to other patients  
39           shall be permitted if an uninsured or underinsured patient is not available.

40           (g) Rules. – The Board shall adopt rules necessary for the implementation of the  
41           Program. Rules adopted by the Board shall provide for the following:

42           (1) Requirements for free clinics and pharmacies to accept and dispense donated  
43           drugs, supplies, and medical devices pursuant to the Program, including  
44           eligibility criteria, confidentiality of donors, and standards and procedures  
45           for a free clinic or pharmacy to accept and safely store and dispense donated  
46           drugs, supplies, and medical devices.

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

- 1           (3)    A list of drugs, supplies, and medical devices, arranged either by category or  
2                   by individual drug, supply, or medical device, that the Program will accept  
3                   for dispensing.
- 4       (h)    Immunity. – The following limited immunities apply under the Program:
- 5           (1)    Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer  
6                   is not subject to criminal or civil liability for injury, death, or loss to a person  
7                   or property for matters related to the donation, acceptance, or dispensing of a  
8                   drug or medical device manufactured by the manufacturer that is donated by  
9                   any person under the Program, including liability for failure to transfer or  
10                  communicate product or consumer information or the expiration date of the  
11                  donated drug or medical device.
- 12          (2)    The following individuals or entities are immune from civil liability for an  
13                  act or omission that causes injury to or the death of an individual to whom  
14                  the drug, supplies, or medical device is dispensed under the Program, and no  
15                  disciplinary action may be taken against a pharmacist or practitioner as long  
16                  as the drug, supplies, or medical device is donated in accordance with the  
17                  requirements of this section:
- 18                  a.     A pharmacy or free clinic participating in the Program.  
19                  b.     A pharmacist dispensing a drug, supplies, or medical device pursuant  
20                  to the Program.  
21                  c.     A practitioner administering a drug, supplies, or medical devices  
22                  pursuant to the Program.  
23                  d.     An eligible donor who has donated a drug, supplies, or a medical  
24                  device pursuant to the Program."

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