

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2009

H

3

HOUSE BILL 1296
Committee Substitute Favorable 5/13/09
Senate Health Care Committee Substitute Adopted 7/15/09

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.** 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.

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

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



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

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

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

13 (1) The drug, supplies, or medical device is in the original, unopened, sealed,
14 and 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 practitioner for use
23 by an eligible patient and is dispensed by a pharmacist.

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

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

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

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

37 (1) Requirements for free clinics and pharmacies to accept and dispense donated
38 drugs, supplies, and medical devices pursuant to the Program, including
39 eligibility criteria, confidentiality of donors, and standards and procedures
40 for a free clinic or pharmacy to accept and safely store and dispense donated
41 drugs, supplies, and medical devices.

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

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

48 (h) Immunity. – The following limited immunities apply under the Program:

49 (1) Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer
50 is not subject to criminal or civil liability for injury, death, or loss to a person
51 or property for matters related to the donation, acceptance, or dispensing of a

1 drug or medical device manufactured by the manufacturer that is donated by
2 any person under the Program, including liability for failure to transfer or
3 communicate product or consumer information or the expiration date of the
4 donated drug or medical device.

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

11 a. A pharmacy or free clinic participating in the Program.

12 b. A pharmacist dispensing a drug, supplies, or medical device pursuant
13 to the Program.

14 c. A practitioner administering a drug, supplies, or medical devices
15 pursuant to the Program.

16 d. An eligible donor who has donated a drug, supplies, or a medical
17 device pursuant to the Program."

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