GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2009

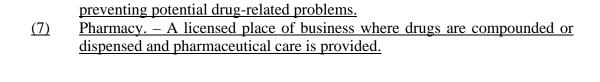
H HOUSE DRH50455-MG-76 (03/26)

(Public)

Est. Drug And Medical Device Repository/DHHS.

Short Title:

Sponsors:	Representative Stewart.
Referred to:	
	A BILL TO BE ENTITLED
	TO ESTABLISH THE DRUG, SUPPLIES, AND MEDICAL DEVICE
	TORY PROGRAM IN THE DEPARTMENT OF HEALTH AND HUMAN
	ES, DIVISION OF PUBLIC HEALTH.
	Assembly of North Carolina enacts:
	ECTION 1. Part 1 of Article 7 of Chapter 130A of the General Statutes is adding the following new section to read:
"§ 130A-216. Drug and medical device repository program established.	
	as used in this section unless the context clearly requires otherwise, the following
definitions apply:	
	Drug. – A human drug required by federal law or regulation to be dispensed
	only by a prescription, including finished dosage forms and active
	ingredients subject to 21 U.S.C. § 353(b).
<u>(</u>	2) Dispense. – To deliver a 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 drug for that delivery.
<u>(</u>	Bligible patient. – An uninsured or underinsured patient who meets the
	eligibility criteria established by the Department, health care facility, or
(pharmacy. Free clinic facility. – A private, nonprofit, community-based organization
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that (i) provides health care services at little or no charge to low-income,

uninsured, and underinsured persons through the use of volunteer health care professionals and partnerships with other health providers and (ii) is licensed

Pharmacist. - A person licensed by the North Carolina Pharmacy Board to

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 identifying potential and actual

drug-related problems, resolving actual drug-related problems, and



by the State.

practice pharmacy.

(5)

(6)

- (8) Practitioner or health care practitioner. A physician or other provider of health services licensed or otherwise permitted to distribute, dispense, or administer drugs or medical devices.
- (9) Supplies. Supplies associated with or necessary for the administration of a drug.
- (b) The Department shall establish and administer a drug and medical device repository program (program). The purpose of the program is to allow a patient or the patient's family to donate unused drugs, supplies to administer the drug, and medical devices to uninsured and underinsured patients in this State. The unused drugs, supplies, and medical devices shall be donated to a free clinic facility or pharmacy that elects to participate in the program. A free clinic facility that receives a donated unused drug, supplies, or medical device under the program may distribute the drug, supplies, or medical device to another free clinic facility or pharmacy for use under the program.
- (c) A pharmacist may accept and dispense drugs, supplies, and medical devices donated to the program to eligible patients if all of the following requirements are met:
 - (1) The drug, supplies, or medical device is in its original, unopened, sealed, and tamper-evident packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened.
 - (2) The pharmacist has determined that the drug, supplies, or medical device is safe for redistribution.
 - (3) The drug bears an expiration date that is later than six months after the date that the drug was donated.
 - (4) The drug, supplies, or medical device is not adulterated or misbranded, as determined by a pharmacist.
 - (5) The drug, supplies, or medical device is prescribed by a health care practitioner for use by an eligible patient and is dispensed by a pharmacist.
- (d) A drug, supplies, or a medical device donated to the program shall not be resold. A free clinic facility or pharmacy may charge an eligible patient a handling fee to receive a donated drug, supplies, or medical device, which shall not exceed the amount specified in rules adopted by the North Carolina Board of Pharmacy.
- (e) Nothing in this section requires a free clinic facility or pharmacy to participate in the program.
- (f) The Department, in consultation with the North Carolina Board of Pharmacy, shall establish eligibility criteria for individuals to receive donated drugs, supplies, or medical devices. Dispensing shall be prioritized to patients who are uninsured or underinsured. Dispensing to other patients shall be permitted if an uninsured or underinsured patient is not available.
- (g) The Department, in consultation with the North Carolina Board of Pharmacy, shall adopt rules necessary for the implementation of the program. Rules adopted by the Department shall provide for the following:
 - (1) Requirements for free clinic facilities and pharmacies to accept and dispense donated drugs, supplies, and medical devices pursuant to the program, including eligibility criteria and standards and procedures for a free clinic facility or pharmacy to accept, and safely store and dispense donated drugs and medical devices.
 - (2) The amount of the maximum handling fee that a free clinic facility or pharmacy may charge for distributing or dispensing donated drugs, supplies, or medical devices.
 - (3) A list of drugs, supplies to administer drugs, and medical devices, arranged either by category or by individual drug, supply or medical device, that the program will accept for dispensing.

Page 2 H1296 [Filed]

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

- The following individuals or entities are immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the drug, supplies, or medical device that is dispensed under the program, and no disciplinary action may be taken against a pharmacist or practitioner as long as the drug, supply, or device is donated in accordance with the requirements of this section.
 - A pharmacy or free clinic facility participating in the program. (1)
 - (2) A pharmacist dispensing a drug, supply, or medical device pursuant to the
 - (3) A practitioner administering a drug or supply pursuant to the program.
 - The donor of a drug, supply, or medical device donated pursuant to the (4) program."
- SECTION 2. Article 4A of Chapter 90 of the General Statutes is amended by adding the following new section to read:

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

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

SECTION 3. There is appropriated from the General Fund to the Department of Health and Human Services, Division of Public Health, the sum of one hundred thousand dollars (\$100,000) for the 2009-2010 fiscal year for the implementation of this act.

SECTION 4. Section 3 of this act becomes effective July 1, 2009. The remainder of this act is effective when it becomes law.

H1296 [Filed] Page 3