21 NCAC 46 .2513 DRUG, SUPPLIES AND MEDICAL DEVICE REPOSITORY PROGRAM

(a) This Rule establishes the Drug, Supplies and Medical Device Repository Program as specified in G.S. 90-85.44.

(b) Definitions. Any term defined in G.S. 90-85.44(a) shall have the same definition under this Rule.

(c) Requirements For a Pharmacy to Participate in Accepting and Dispensing Donated Drugs, Supplies and Medical Devices.

(1) Any pharmacy or free clinic holding a valid, current North Carolina pharmacy permit may accept and dispense donated drugs, supplies and medical devices in accordance with the requirements of this Rule and G.S. 90-85.44.

(2) A dispensing physician registered with the Board in compliance with G.S. 90-85.21(b) and providing services to patients of a free clinic that does not hold a pharmacy permit may accept and dispense donated drugs, supplies and medical devices in accordance with the requirements of this Rule and G.S. 90-85.44.

(3) A participating pharmacy or dispensing physician shall notify the Board in writing of such participation at the time participation begins and annually on its permit or registration renewal application.

(4) A participating pharmacy or dispensing physician that ceases participation in the program shall notify the Board in writing within 30 days of doing so and shall submit a written report detailing the final disposition of all donated drugs, supplies and medical devices held by the participating pharmacy or dispensing physician.

(d) Drugs, Supplies and Medical Devices Eligible for Donation.

(1) A participating pharmacy or dispensing physician may accept donation of a drug, supply or medical device meeting the criteria specified in G.S. 90-85.44(c).

(2) The following categories of drugs, supplies and medical devices shall not be accepted by a participating pharmacy or dispensing physician:

(A) A controlled substance, unless acceptance of a donated controlled substance is authorized by federal law.

(B) Any prescription drug or medical device subject to a restricted distribution system mandated by the United States Food and Drug Administration.

(C) Biologicals, unless donated by the manufacturer or a prescription drug wholesaler. A pharmacy may donate a biological if the biological has been stored according to the manufacturer's labeling and has not previously been dispensed to a patient or other person.

(D) Compounded drugs or parenteral admixtures.

(E) Any drug requiring refrigerated storage, unless donated by either (a) the manufacturer, (b) a prescription drug wholesaler or (c) a pharmacy that has stored the drug according to the manufacturer's labeling and has not previously dispensed the drug to a patient or other person.

(e) Required Records.

(1) A participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall maintain a written or electronic inventory of each donated drug, supply and medical device that shall include the following:

(A) The name, strength, dosage form, number of units, manufacturer's lot number and expiration date.

(B) The name, address and phone number of the eligible donor providing each drug, supply or medical device.

(2) A participating pharmacy or dispensing physician shall keep all donated drugs, supplies and medical devices physically separated from other inventory. The physically separate storage area for donated drugs, supplies and medical devices shall be identified.

(3) In addition to all records required for dispensing a prescription drug, supply or medical device under the North Carolina Pharmacy Practice Act and rules, a participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall note – either on the face of a written prescription or in the electronic record of a prescription – that a donated prescription drug, supply or medical device was dispensed to the patient.

(4) A participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall maintain patient-specific written or electronic documentation of any dispensing of a donated non-prescription drug, supply or medical device.

(f) Eligible Patient.

(1) A participating pharmacy or dispensing physician shall establish and maintain a written patient eligibility policy that shall conform to the priorities specified in G.S. 90-85.44(f).

(2) Donated drugs, supplies or medical devices shall be dispensed to patients who are residents of North Carolina and meet the participating pharmacy's or dispensing physician's eligibility criteria.

(g) Handling Fee.

(1) A participating pharmacy or dispensing physician may charge a prescription drug handling fee to an eligible patient that shall not exceed the co-payment established by North Carolina Medicaid and required of a North Carolina Medicaid beneficiary who receives the same prescription drug in the same quantity.

(2) A participating pharmacy or dispensing physician may charge a medical device or supply handling fee to an eligible patient that shall not exceed the co-payment established by North Carolina Medicaid and required of a North Carolina Medicaid beneficiary to whom a brand-name prescription drug is dispensed.

(3) Nothing in this Rule shall require a participating pharmacy or dispensing physician to charge an eligible patient a handling fee, nor shall a participating pharmacy or dispensing physician charge a handling fee where doing so is otherwise prohibited by law.

(h) Confidentiality of Records.

(1) A participating pharmacy or dispensing physician that dispenses donated drugs, medical devices or supplies to an eligible patient shall remove or alter any labeling or other material from a donated drug, supply or medical device that could identify the patient to whom the donated product was originally dispensed so that the identity of that patient cannot be determined.

(2) Records required by this Rule shall be governed by the confidentiality provisions of G.S. 90-85.36 and the Health Insurance Portability and Accountability Act of 1996.

(3) Records required by this Rule shall be maintained by the participating pharmacy or dispensing physician for a period of three years.

History Note: *Authority G.S. 90-85.6; 90-85.26; 90-85.32; 90-85.44;*
Eff. June 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.