

FREQUENTLY ASKED QUESTIONS ABOUT DONATION AND DISPENSING OF PRESCRIPTION DRUGS, DEVICES, AND MEDICAL SUPPLIES

1. Can prescription drugs, devices, and medical supplies be donated for redispensing?

In certain circumstances, described further below, yes. North Carolina statute (NCGS 90-85.44) and Board of Pharmacy rules (21 NCAC 46.2513) govern donation and redispensing.

2. Who can accept and dispense donated drugs, supplies, and medical devices in the program? (1) Any pharmacy holding a current North Carolina pharmacy permit; (2) a “free clinic”* that has a valid North Carolina pharmacy permit; and (3) a dispensing physician who is registered with the Board of Pharmacy and provides services to patients of a free clinic that does not hold a pharmacy permit.

*The statute defines a “free clinic” as “a private, nonprofit, community-based organization that provides health care services at little or no charge to low-income, uninsured, and underinsured persons through the use of volunteer health care professionals.” Note that a “free clinic” must have a valid North Carolina pharmacy permit (or a registered dispensing physician) to dispense any prescription drugs, whether donated or not.

3. I’m interested in donating drugs (devices or supplies). Who can I contact about fee and charitable clinics near me? The North Carolina Association of Free Clinics, <http://www.ncfreeclinics.org>, (336) 251-1111, may be able to assist you in locating a pharmacy or clinic that will accept a donation.

4. What notification must a pharmacy or dispensing physician who plans to accept and dispense donated drugs, supplies, and medical devices provide to the Board of Pharmacy? Participants must notify the Board in writing at the start of participation in the program and on the participant’s permit or registration renewal annually. There is no “form” for notifying the Board. A letter or fax suffices.

5. What drugs, devices, and supplies are eligible for donation?

- Any drug, supply, or medical device in the original, unopened, sealed and tamper-evident packaging; (i.e. manufacture’s packaging) with an expiration date that is at least six (6) months after donation.
- Prescription drugs that have been unit-dose packaged if the unit dose packaging is unopened, the drug labeled appropriately, and the expiration date is six (6) months

from the date of donation.

6. What drugs, devices, and supplies are not eligible for donation?

- Any drug, device, or supply that does not meet the criteria listed in Question 4 above is not eligible for donation. This means, for instance, that prescription drugs that have been dispensed to patients in amber vials (or similar) are not eligible for donation.
- Controlled substances
- Any prescription drug or medical device that has restricted distribution by the FDA. Examples include thalidomide, isotretinoin, Zyprexa Relprevv (olanzapine) extended release injection, rosiglitazone maleate. More complete information about drugs subject to FDA-mandated restricted distribution systems may be found here:
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm#Additional_REMS_information
- Compounded drugs or parenteral admixtures
- Biologicals and any drug requiring refrigeration, unless such drugs are donated by the manufacturer, a prescription drug wholesaler, or a pharmacy that has stored the drug/biological according to manufacturer's labeling. A biologic or drug requiring refrigeration may not be donated even by the manufacturer, a wholesaler, or a pharmacy if the drug has been previously dispensed to a patient.

7. Who can donate drugs, supplies, and medical devices?

- A patient or the patient's family member. Note: As discussed in Question 3 above, any donated drug, device, or supply must be in the manufacturer's original, sealed packaging or in unopened unit dose packaging. This, as a practical matter, greatly reduces the amount of prescription drugs eligible for donation from patients or patient family members .
- A manufacturer, wholesaler or supplier of drugs, supplies or medical devices
- A pharmacy, free clinic, hospital or hospice care program.

8. Which patients are eligible to receive donated drugs, supplies and medical devices?

Donated drugs, supplies, and devices may be dispensed to North Carolina residents. Dispensing pharmacies and clinics must establish written patient eligibility policies that give priority to patients who are “uninsured or underinsured.” If “uninsured or underinsured” patients are not available to receive dispensing, the pharmacy or clinic may dispense to other patients in conformance with the written eligibility policy.

9. Can a pharmacy or free clinic charge a handling fee when dispensing donated drugs, supplies, and medical devices? Yes. But the fee may 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. Neither the statute nor Board rule requires that a handling fee be charged.

Note: Resale of donated drugs, supplies, and devices is expressly prohibited.

10. What records are required for a participating pharmacy or dispensing physician that dispenses donated drugs, supplies, or medical devices?

The pharmacy or dispensing physician who dispenses donated drugs, supplies, or devices must maintain a written or electronic inventory of each donated drug, supply and medical device that includes:

- Name of the donated drug, supply or medical device
- Strength
- Dosage form
- Number of units donated
- Manufacturer’s lot number
- Expiration date
- Name, address and phone number of the donor that provided each drug, supply or medical device.

When a donated drug, supply, or device is dispensed to a patient:

- The fact that a donated items was dispensed must be recorded on the face of the written prescription or in the electronic record of the prescription.
- Patient-specific written or electronic documentation of any dispensing of a donated non-prescription drug, supply or medical device should also be

maintained.

Note: These recordkeeping requirements apply to the dispenser of donated items. The donor is not required to create and maintain such records for purposes of the donation statute and rules.

11. Must donated drugs, supplies and medical devices be physically separated from non-donated inventory? Yes. And the inventory area holding donated drugs, supplies, and devices must be clearly identified.

12. If a pharmacy or dispensing physician ceases participation in a donation program what procedure should be followed? The participant should notify the board in writing within 30 days and submit a written report that includes details on the final disposition of all donated drugs, supplies and medical devices.

13. Does the donation statute provide any protections for donors of drugs, devices, and supplies or pharmacies/clinics that dispense donated items? Yes. The statute provides immunity from civil liability relating to the donation or dispensing of drugs, devices and supplies as follows:

Pharmaceutical Manufacturer: Unless a pharmaceutical manufacturer exercises bad faith, the manufacturer is not 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.

Other Donors, Pharmacies, Pharmacists, Clinics, Physicians, Practitioner that Administers a Donated Drug, Device or Supply: Each 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 is dispensed, and no disciplinary action may be taken against a pharmacist or practitioner as long as the drug, supplies, or medical device is donated in accordance with the statute and rules governing such donation and dispensing.