

ALABAMA DEPARTMENT OF PUBLIC HEALTH
STATE COMMITTEE OF PUBLIC HEALTH
ADMINISTRATIVE CODE

CHAPTER 420-11-1
PROCEDURES FOR DONATION OF CERTAIN PRESCRIPTION DRUGS TO
CHARITABLE CLINICS

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420-11-1-.01 Definitions.

When used herein, the following words and terms shall have the meaning hereinafter ascribed to them unless the context prohibits.

(1) Charitable clinic - An established free medical clinic as defined in subdivision (1) of Section 4 of Act No. 2000-680 and any community health center provided for under the United States Public Health Service Act.

(2) Charitable patient - A person who is a recipient of services of a charitable clinic but shall not include people who are eligible to receive drugs under the Alabama Medicaid Program or under any other prescription drug program funded in whole or in part by the State of Alabama.

(3) Legend drug - Any substance required to bear or that bears upon the label the words "Caution, Federal Law Prohibits Dispensing Without A Prescription" or "RX Only" or similar wording.

(4) Donating patient - A person who is a recipient of services in an authorized institution as defined in this rule.

(5) Physician - A person currently licensed by the Alabama Medical Licensure Commission to practice medicine and surgery in Alabama. The use of the word, "physician" in this rule shall not be deemed to preclude a properly licensed nurse practitioner or a physician's assistant from performing any function that is within that individual's scope of practice.

(6) Pharmacist - A person licensed by the Alabama Board of Pharmacy to practice pharmacy.

(7) Unit dose - Medication packaged in individually sealed pockets in a card.

(8) Authorized institution - A licensed hospital, nursing facility, intermediate care facility, assisted living facility, specialty care assisted living facility, or hospice in Alabama.

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420-11-1-.02 Procedures.

(1) Legend drugs dispensed to a patient except controlled substances may be donated by the patient or, if the patient is deceased or incompetent, the patient's spouse, an adult child, a brother or sister, either parent, a legally-appointed guardian, or the administrator of the estate of a deceased patient.

(2) The physician or pharmacist associated with the charitable clinic shall ensure that the drugs that are accepted for use by the charitable clinic meet the following criteria:

(a) The drugs are no longer needed by the original patient due to death or a stop order by the patient's physician.

(b) The drugs have been maintained in accordance with the United States Pharmacopeia and National Formulary storage requirements.

(c) The drugs were originally dispensed by unit dose or an individually sealed dose and they are still intact in the original dispensed container. Medications in a bulk container are only acceptable from a hospice program.

(d) The drugs have not expired. The drugs must be used prior to the expiration date on the package.

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420-11-1-.03 Transfer Of Drugs.

Charitable clinics must have a written agreement with an authorized institution before accepting drugs. The following procedures must be followed by the authorized institution before releasing custody of the medications to the charitable clinic.

(1) Any person accepting custody of donated prescription medications on behalf of a charitable clinic shall have written authorization from the charitable clinic's administrator to do so.

(2) An institution transferring custody of drugs shall have on file written documentation that the patient or family member donated the drugs to the charitable clinic. The documentation shall be maintained for a minimum of two years at the institution.

(3) The prescription container shall have any specific patient identifying information removed from or made illegible on the container.

(4) The name, strength, and expiration date of the drug must remain on the container.

(5) The person who releases the drugs to the delivery or pick-up person for the charitable clinic shall provide an inventory list of the drugs to the delivery or pick-up person that includes the name of the medication, strength, expiration date, and quantity. The list must be dated and signed by the person releasing the medication from the transferring institution. The delivery or pick-up person must sign and date the list to be maintained at the institution transferring custody of the drugs. The list must be signed and dated by a representative of the charitable institution that receives the medication and a copy maintained at the charitable institution for a period of at least two years. The medications must be physically transferred within seven days of notification that they are available.

(6) All records of the transfer will be open to inspection by the Board of Pharmacy, Board of Medical Examiners, Alabama Department of Public Health, and law enforcement officials in Alabama.

(7) Charitable clinics may give donated drugs only to charitable patients as defined by these rules.

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