House Bill 430
By: Representatives Hill of the 180th, Keen of the 179th, Smith of the 70th, Cooper of the 41st, Rynders of the 152nd, and others

A BILL TO BE ENTITLED
AN ACT

To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to enact "Karon’s Law"; to provide for a short title; to provide for the establishment and operation of a drug repository program to accept and dispense donated prescription drugs; to provide for definitions; to provide for criteria for the acceptance of drugs into the program; to provide for persons and entities who are authorized to donate drugs to the program; to provide for entities that may accept and dispense donated drugs; to limit the liability for drug manufacturers and for persons and entities participating in the program; to provide for the establishment of rules and regulations by the State Board of Pharmacy for the implementation and operation of the program; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.
Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by adding a new Article 11 to read as follows:

"ARTICLE 11

26-4-190. This article shall be known and may be cited as 'Karon’s Law.'

26-4-191. As used in this article, the term:

(1) 'Health care facility' means an institution which is licensed as a hospital or nursing home pursuant to Article 1 of Chapter 7 of Title 31 or licensed as a hospice pursuant to Article 9 of Chapter 7 of Title 31, or a home health agency licensed pursuant to Article 7 of Chapter 7 of Title 31.
(2) 'Health care professional' means any of the following who provide medical, dental, or other health related diagnosis, care, or treatment:

(A) Individuals licensed to practice medicine under Chapter 34 of Title 43;
(B) Registered nurses and licensed practical nurses licensed under Chapter 26 of Title 43;
(C) Physician assistants authorized to practice under Chapter 34 of Title 43;
(D) Dentists and dental hygienists licensed under Chapter 11 of Title 43;
(E) Optometrists licensed under Chapter 30 of Title 43; and
(F) Pharmacists licensed under Chapter 4 of this title.

(3) 'Hospital' means a facility which has a valid permit or provisional permit issued under Chapter 7 of Title 31 and which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons.

(4) 'Indigent person' means any person having as a maximum allowable income level an amount corresponding to 125 percent of the federal poverty guideline.

(5) 'Nonprofit clinic' means a charitable nonprofit corporation organized and operated pursuant to Chapter 3 of Title 14 that provides health care services to indigent and uninsured persons. 'Nonprofit clinic' shall not include a hospital.

(6) 'Program' means the drug repository program established pursuant to Code Section 26-4-192.

26-4-192.

The board shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this state and meet eligibility standards established in rules adopted by the board pursuant to Code Section 26-4-195. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated pursuant to Code Section 26-3-7. Subject to the limitation specified in this Code section, unused drugs dispensed for purposes of the Medicaid program may be accepted and dispensed under the drug repository program.
26-4-193.
(a) Any person, including a drug manufacturer or any health care facility, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the board under Code Section 26-4-195. Participation in the program by pharmacies, hospitals, and nonprofit clinics is voluntary. Nothing in this or any other Code section shall require a pharmacy, hospital, or nonprofit clinic to participate in the program.

(b) A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated under this Code section to individuals who are residents of this state and meet the eligibility standards established in rules adopted by the board pursuant to Code Section 26-4-195 or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a valid prescription drug order. A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal laws and laws of this state dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in accordance with rules adopted by the board pursuant to Code Section 26-4-195. Drugs donated to the repository may not be resold.

26-4-194.
(a) The State Board of Pharmacy; the commissioner of the Department of Human Resources; any person, including a drug manufacturer, or government entity that donates drugs to the program; any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program shall not, in the absence of bad faith, be subject to criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional disciplinary action for matters related to donating, accepting, or dispensing drugs under the program.

(b) A drug manufacturer shall not, in the absence of bad faith, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.
In consultation with the commissioner of the Department of Human Resources, the board shall establish rules and regulations governing the drug repository program that establish all of the following:

(1) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense donated drugs under the program;
(2) Standards and procedures for accepting, safely storing, and dispensing donated drugs;
(3) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe, and suitable for dispensing;
(4) Eligibility standards based on economic need for individuals to receive drugs;
(5) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;
(6) A form that an individual receiving a drug from the repository must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program;
(7) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;
(8) For drugs donated to the repository by individuals:
   (A) A list of drugs, arranged either by category or by individual drug, that the repository will accept from individuals;
   (B) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from individuals, including a statement as to why the drug is ineligible for donation; and
   (C) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository;
(9) For drugs donated to the repository by health care facilities:
   (A) A list of drugs, arranged either by category or by individual drug, that the repository will accept from health care facilities; and
   (B) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from health care facilities, including a statement as to why the drug is ineligible for donation; and
(10) Any other standards and procedures the board considers appropriate.”
SECTION 2.

All laws and parts of laws in conflict with this Act are repealed.