



2 December 2016

NOTICE OF PROPOSED RULEMAKING

Proposed New Public Health Regulation

Chapter 511-5-12 “Donated Drug Repository Program”

Please take note that the Department of Public Health proposes to enact Chapter 511-5-12 “Donated Drug Repository Program” pursuant to its authority under O.C.G.A. § 31-2A-6 and 31-8-304.

House Bill 897 (2016) requires the Department to implement a program whereby authorized entities may accept and dispense donated over-the-counter and prescription drugs. Code Section 31-8-304 requires the Department to promulgate regulations to set criteria for eligible recipients; criteria for eligible patients to receive donated drugs, including priorities for patients who are indigent, uninsured, or overinsured, or enrolled in a public assistance health benefits program; standards and procedures for safely storing and dispensing donated drugs; and handling fees that may be charged by eligible recipients to eligible patients to cover restocking, marketing, administrative, and dispensing costs.

Interested persons may submit comments on these proposed revisions in writing addressed to:

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General Counsel
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2 Peachtree Street, NW
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Comment may also be presented in person at a public meeting scheduled for 1:00 p.m., 28 December 2016, in room 9-260 at 2 Peachtree Street, NW, 15th Floor, Atlanta GA.



Sidney R. Barrett, Jr.
General Counsel



RULES OF THE DEPARTMENT OF PUBLIC HEALTH
CHAPTER 511-5-12

Donated Drug Repository Program

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511-5-12-.01 Definitions

As used in this Chapter, the term:

(1) **“Controlled substance”** means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308.

(2) **“Drugs”** mean both prescription drugs and non-prescription (“over-the-counter”) drugs.

(3) **“Eligible patient”** means an indigent person; provided, however, that if the recipient’s supply of donated drugs exceeds the need for donated drugs by indigent patients, any other person in need of a particular drug can be an eligible patient, so long as priority is given to persons who are under 18 years of age, over 65 years of age, pregnant, or disabled.

(4) **“Eligible recipient”** means a pharmacy, hospital, federally qualified health center, nonprofit clinic, healthcare facility, or private office of a healthcare professional which has been approved by the Office of Pharmacy of the Department of Public Health as provided in DPH Rule 511-5-12-.02.

(5) **“Health care facility”** means a facility licensed by the Georgia Department of Community Health in accordance with Title 31, Chapter 7 as a:

(A) Nursing home;

(B) Personal care home;

(C) Assisted living community;

(D) Hospice;

(E) Hospital; or

(E) Home health agency.

(6) **“Health care professional”** means a person who is licensed by the State of Georgia to practice as a:

(A) Physician;

(B) Registered nurse or licensed practical nurse;

(C) Physician assistant;

(D) Dentist or dental hygienist;

(E) Optometrist; or

(F) Pharmacist.

(7) **“Indigent patient”** means a patient whose income is at or below the income eligibility requirements of the Georgia Medicaid program, uninsured, underinsured, or enrolled in a public assistance health benefits program.

(8) **“Program”** means the donated drug repository program established by this Department pursuant to Code Section 31-8-301.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.02 Eligible recipients.

(1) A pharmacy, hospital, federally qualified health center, nonprofit clinic, healthcare facility, or healthcare professional that is otherwise legally authorized to possess and dispense prescription drugs may become an eligible recipient for a period of one year by giving written notice to the Office of Pharmacy of the Department of Public Health. That notice shall serve as

authority for the recipient to participate in the program for a period of one year, unless revoked by this Department. An eligible recipient may renew its authority by sending written notice in subsequent years.

(2) An entity which chooses to participate in the program shall comply with this Chapter, and shall make records of its receipt and distribution of drugs available for audit by this Department or its designee during business hours. Failure to comply with any provision of this Chapter or the statutes and regulations governing prescription drugs may result in revocation of authority to participate in the program.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.03 Criteria for donated drugs.

(1) The drugs shall be donated in unopened tamper-evident packaging as defined by United States Pharmacopeial Convention (USP) standards, Chapter 659, Packaging and Storage Requirements.

(2) Prior to and during transport to the eligible recipient, the drugs must be kept in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeial Convention (USP) standards.

(3) Drugs are eligible for donation if they will not expire within 90 days from the date of transfer to the eligible recipient.

(4) Drugs which have been adulterated or misbranded as defined in O.C.G.A. Sections 26-3-7 and 26-3-8 may not be donated or accepted as donations.

(5) The following categories of drugs shall not be accepted into the repository program

(A) Controlled substances;

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

(C) Biologicals, unless donated by the manufacturer or a licensed drug wholesaler. A pharmacy may donate a biological if it 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; and

(E) Any drug requiring refrigerated storage, unless donated by either the manufacturer or a licensed drug wholesaler.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.04 Donation of drugs to an eligible recipient.

(1) A drug manufacturer, wholesaler, reverse distributor, pharmacy, third-party logistics provider, government entity, hospital, or health care facility holding a permit in good standing with the Georgia Board of Pharmacy may donate drugs.

(2) Before donating drugs to an eligible recipient, the donor must determine that the drug is suitable to be dispensed to a patient, including but not limited to the following measures:

(A) If the drug was previously dispensed, verify that

1. Patient or patient's agent has authorized donation of the drug, the patient has died, or that the drug has been discontinued by the donor;
2. The name of the patient, name of the pharmacy, and directions on the label have been removed or redacted; and
3. The drug has been kept under the control of a health care professional.

(B) In all cases, verify that the drug has been stored properly, is properly identified, has not been adulterated, and will not expire for at least 90 days from the date of transfer to the eligible recipient;

(3) At the time of donation, the donor must provide a manifest to the eligible recipient which includes the following information:

1. Serial number;
2. The date transferred to the eligible recipient;
3. Name and strength of the drug, lot number, expiration date of the drug, and number of tablets or capsules, or volume if liquid or injectable;
4. A signed statement that the drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturer's recommendations and United States Pharmacopeial Convention (USP) standards;
5. For long term care facilities, nursing homes, and assisted living facilities, the manifest shall include the printed names and signatures of the Consultant Pharmacist and Director of Nursing or designee, facility name and address, and phone number;

6. For all other licensed health care facilities and healthcare professionals, the manifest shall include the printed name and signature of a healthcare professional, the healthcare professional's license number, facility or office name and address, and phone number;

7. For drug manufacturers, wholesalers, reverse distributors, and third-party logistics providers, the manifest shall include the printed name and signature of the distribution manager, facility Board of Pharmacy license number, facility name and address, and phone number.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.05 Receipt, storage, and handling of donated drugs by an eligible recipient.

(1) An eligible recipient must store and maintain donated drugs in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeial Convention (USP) standards. This statement must accompany the drugs to the receiving eligible recipient.

(2) The eligible recipient must ensure the removal or redaction of the original patient's name, doctor's name, prescription number, and any material that could identify the patient to whom the donated product was originally dispensed, so that the identity of that patient cannot be determined from the label on the donated drug.

(3) A participating eligible recipient shall keep all donated drugs physically separated from other inventory in a separate storage area identified for donated drugs.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.06 Dispensing and distribution of donated drugs.

(1) Donated prescription drugs may only be dispensed to eligible patients pursuant to a valid prescription drug order in accordance with Title 26, Chapter 4. The patient shall be provided with appropriate counseling on the use of the prescription drug and any potential side effects, and informed that the drug was donated.

(2) An eligible recipient may transfer unused prescription drugs to or receive unused prescription drugs from another eligible recipient in the program when one has the need for a drug and another has it available. A manifest of such transfers shall be created in accordance with DPH Rule 511-5-12-.04(3).

(3) If an eligible recipient receives donated drugs that cannot be dispensed, the eligible recipient may return the drug to the donor, destroy the drug, or transfer it to a reverse distributor for destruction. The receiving eligible recipient must document the disposal of such donated drugs on a readily retrievable log. All such donated drugs to be disposed shall be

maintained in a separately designated area from purchased stock of drugs, and such storage shall be in an area to ensure drug integrity.

(4) Donated drugs shall not be resold; provided, however, that reimbursement for any handling fee authorized pursuant to this Chapter shall not constitute reselling.

(5) Before dispensing a donated drug, all previous patient information and pharmacy labeling must be redacted or removed.

(6) Dispensed drugs must clearly indicate the final dispenser's information and current patient information, and shall be properly labeled in accordance with the regulations of the Georgia Board of Pharmacy.

(7) An expiration date is required on all donated drugs dispensed. The expiration date shall be brought forward to the filled prescription. If multiple packages of donated drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date shall be used for the dispensed prescription.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.07 Required records.

(1) A participating eligible recipient shall maintain a written or electronic inventory of each donated drug received, including:

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

(b) The name, address and phone number of the donor who provided each donated drug, and the manifest serial number.

(2) An eligible recipient that provides donated drugs to an eligible patient shall maintain patient-specific written or electronic documentation in accordance with Georgia law and the regulations of the Board of Pharmacy, including but not limited to the manifest number. The eligible recipient also shall note, either on the face of a written prescription or in the electronic record of a prescription, that a donated drug was dispensed to the patient.

(3) If drugs are transferred to or received from another eligible recipient in the program, then the transfer shall be documented on a manifest and maintained by both parties for two years.

(4) If an eligible recipient disposes of donated drugs by properly destroying them or using a reverse distributor, then the disposition shall be documented on a readily retrievable log and maintained for two years.

(5) All records required by this Chapter shall be maintained and protected in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), FDA requirements including Public Law 113-54, and any other applicable state and federal privacy laws

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.

511-5-12-.08 Handling fees.

An eligible recipient may not charge or collect any fees from an eligible patient for drugs dispensed pursuant to this program; provided, however, that an eligible recipient may charge a small handling fee for each donated drug that is dispensed. Such a handling fee shall not exceed the reasonable costs of participating in the program or the dispensing fee established by Georgia Medicaid for the same quantity of such drug, and shall not exceed \$11.00 for medications not covered by Georgia Medicaid.

Authority: O.C.G.A. Sections 31-2A-6 and 31-8-304.