Rules of the Department of Public Health
Chapter 511-5-12-0.1

Donated Drug Repository Program

511-5-12-0.1-.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 CFR Part 1308.
(2) "**Donor**" shall mean any person, including an individual member of the public, or any entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, including but not limited to a wholesaler or distributor, third party logistic providers, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation centers, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor shall also mean government agencies and entities that are federally authorized to possess drugs including but not limited to drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, and prisons.
(3) "**Drugs"** means both prescription and non-prescription ("over-the-counter") drugs.
(4) "**Eligible patient**" means an indigent person; provided, however, that if the recipient's supply of donated drugs exceed the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.
(5) "**Eligible recipient**" means a pharmacy, wholesaler, reverse distributor, hospital, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state's law, or private office of a healthcare professional which has been authorized by the Office of Pharmacy of the Department of Public Health as provided in DPH Rule 511-5-12-0.1-.04.
(6) "**Healthcare 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) Residential care facility for the elderly;

(e) Hospice;
(f) Hospital;
(g) Home health agency; or
(h) A similar entity licensed in the state in which it is located.
(7) "**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
(8) "**Indigent patient**" means a patient whose income is at or below the income eligibility requirements of the Georgia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.
(9) "**Program**" means the donated drug repository program established by this Department pursuant to Code Section 31-8-301.
(10) "**Transaction date**" means the date on which ownership of the drugs is transferred between two participants of the program as established by contract or other arrangement. If no such contract or arrangement exists, the transaction date shall be the date the drug was accepted into inventory by the recipient.

Authority: Code Sections 31-2A-6 and 31-8-304.

511-5-12-0.1-.02 Authority and waivers.

(1) A donor or eligible recipient may request a waiver from the Department of Public Health for any regulation or law related to this program. Request for a waiver must be submitted in writing and include the specific requirements requested to be waived and the reason the waiver is necessary. The Department of Public Health shall determine within 30 days whether to grant or deny a waiver based on the potential effects to drug access and safety for eligible patients. If denied, the Department shall respond to the request with the specific reasons for denial based on their effect to drug access and safety for eligible patients and if any alternatives exist. If granted, the Department shall publish the granted waiver and the requestor's submission on its website.
(2) Pursuant to Code Section 31-8-304, this Department and its rules have sole regulatory authority over the program. Notwithstanding any other administrative regulation, including but not limited to Ga. R. & Regs.
(a) 480-10-.17, 480-24-.05(2)(b), and 480-24-.06, a person or entity may dispose of an eligible drug by donating it to an eligible recipient in accordance with the rules of this program.
(b) 480-10-.21 and 480-16-.08, an eligible recipient including but not limited to a pharmacy may receive drugs from a donor as defined in 511-5-12-.01-0.1(2) in accordance with the rules of this program.

(c) 480-7-.03(7)(e)(1), an eligible recipient may accept donated drugs that are in tamper-evident packaging in accordance with DPH Rule 511-5-12-0.1-.03(1)(b), including but not limited to drugs that have a tamper-evident seal on either their immediate, outer, secondary, or shipping container.
(d) 480-7.02(1)(d), an eligible recipient, including but not limited to a pharmacy, may receive, accept, replenish, repackage, and store donated drug samples in accordance with the rules of this program.

Authority: Code Sections 31-2A-6 and 31-8-304.

511-5-12-0.1-.03 Eligible drugs.

(1) Drugs shall only be dispensed pursuant to the program if:
(a) For prescription drugs, they do not expire before the completion of the medication by the eligible patient based on the prescribing health care professional's directions for use and, for over-the-counter drugs, they do not expire before use by the eligible patient based on the directions for use on the manufacturer's label; and
(b) The drugs were donated in unopened tamper-evident packaging as defined by United States Pharmacopeia General Chapter 659, Packaging and Storage Requirements, including but not limited to unopened unit-dose and multiple-dose packaging.
(2) The following drugs shall not be donated to the program:
(a) Controlled substances;
(b) Drugs subject to a federal Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. Section 355-1 if inventory transfer is prohibited by such strategy; or
(c) Drugs that there is reason to believe are adulterated pursuant to Code Section 26-3-7.

Authority: Code Sections 31-2A-6 and 31-8-304.

511-5-12-0.1-.04 Eligible recipients.

(1) A pharmacy, hospital, wholesaler, reverse distributor, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state's law, or healthcare professional that is otherwise legally authorized to possess 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 the Department. An eligible recipient may renew its authority by sending written notice in subsequent years.
(2) The Department of Public Health shall publish on its website the list of authorized recipients.
(3) An entity which chooses to participate in the program shall comply with this Chapter, and shall make all records available for audit by this Department within five business days. Failure to comply with any provision of this Chapter or statutes governing prescription drugs may result in

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revocation of authority to participate in the program. Such revocation shall be provided as a written notice to the recipient and shall include the specific requirements that were violated and the corrective actions necessary for the recipient to reinstate its authority to participate in the program.

Authority: Code Sections 31-2A-6 and 31-8-304.

511-5-12-0.1-.05 Receipt, storage, and handling of donated drugs by an eligible recipient.

(1) A donor may donate drugs to an eligible recipient.
(2) An eligible recipient may receive, accept, donate, dispose, replenish, and store drugs that were either donated or repackaged as provided in paragraph (6) of this Rule.
(3) Prior to the first donation from a new donor, a recipient must verify and record the following:
(a) The donor meets the definition provided in DPH Rule 511-5-12-0.1-.01(2);
(b) The donor's name, address, phone number, and license number if applicable;
(c) The donor will only make donations of drugs in accordance with Code Section 31-8-301;
(d) The donor will insure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by enclosing in the drug's packaging a USP-recognized method by which the eligible recipient can easily detect improper storage or temperature variations; and
(e) If applicable, the donor will remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the eligible recipient.
(4) 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.
(5) A participating eligible recipient shall keep all donated drugs physically or electronically separated from other inventory. Donated inventory may be used to replenish purchased inventory with the same drug name and strength that was previously dispensed or administered to an eligible patient. Replenishment shall follow applicable federal 340B statute and Health Resources and Services Administration guidance.
(6) Drugs may be repackaged as necessary for storage, replenishment, dispensing, administration, or further donation. Repackaged drugs shall be labeled with the drug name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a health care professional.
(7) All donations received but not yet accepted into inventory shall be kept in a separate designated area.
(8) Prior to or upon accepting a donation into inventory, an eligible recipient shall maintain a written or electronic inventory of the donation, including:
(a) The transaction date;
(b) The name, strength, and quantity of each accepted drug; and
(c) The name, address and phone number of the donor.

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(9) No record of a donation other than as described in paragraph (8) of this Rule shall be required.
(10) All records required by this Chapter shall be retained in physical or electronic format, on or off the recipient's premise for a period of six years.
(11) A donor or eligible recipient may contract with one another or a third-party to create and/or maintain records on each other's behalf.
(12) An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label pursuant to this Chapter if it allows for such information to be readily retrievable. Upon audit by the Department of Public Health the identifier on requested records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.
(13) Pursuant to Code Section 26-4-115(b)(3)(A), a drug wholesaler, distributor, supplier, or outsourcing facility registered as provided in Chapter 13 of Title 16 or in Code Section 26-4-115(a), except reverse distributors, shall comply with the requirements of 21 U.S.C. Sections 360eee-1 through 360eee-4 relating to drug supply chain security. If a donation's transaction history is required, the record of transaction history shall begin with the donor of the drugs, shall include all subsequent donations, and, if the drug was previously dispensed, shall only include drug information required to be on the drug's label pursuant to Code Section 26-4-80(k)(1).

Authority: Code Sections 31-2A-6 and 31-8-304.

511-5-12-0.1-.06 Dispensing and distribution of donated drugs.

(1) An eligible recipient may only dispense or administer prescription drugs if otherwise permitted by law.
(2) Donation and the brokering or other facilitation of a donation of a drug pursuant to this program shall not be considered wholesale distribution and shall not require licensure as a wholesaler.
(3) Donated prescription drugs may only be dispensed to eligible patients pursuant to a valid prescription drug order in accordance with Title 26, Chapter 4. That patient shall be provided with appropriate counseling on the use of the prescription drug, including any potential side effects and the fact that the drug was donated.
(4) An eligible recipient may further donate 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. An inventory of such donations shall be created in accordance with DPH Rule 511-5-12-0.1-.05(8) unless both eligible recipients are under common ownership or common control.
(5) An eligible recipient shall dispose of any drug that does not meet all of the requirements of Code Section 31-8-301 in one of the following ways:
(a) Return the drug to the donor;
(b) Destroy the drug through an incinerator licensed with the Environmental Protection Agency or other lawful method; or
(c) Transfer the drug to a reverse distributor.

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(6) All such donated drugs to be disposed shall be ~~maintained~~ quarantined in a separately designated area
(7) An eligible recipient shall maintain a written of electronic record of disposal, including:
(a) The disposal method as described in paragraph (5) of this Rule;
(b) The date of disposal or quarantine; and
(c) The name, strength, and quantity of each drug disposed.
(8) No record of disposal other than as described in paragraph (7) of this Rule shall be required.
(9) Donated drugs shall not be resold and shall be considered nonsaleable; provided, however, that reimbursement for any handling fee authorized pursuant to this Chapter shall not constitute reselling.
(10) Before dispensing a donated drug, an eligible recipient shall inspect the drug to determine that it has not adulterated. The drug must be repackaged into a new container or all previous patient information and pharmacy labeling must be redacted or removed from the donated container.
(11) 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.
(12) An eligible recipient that provides donated drugs to an eligible patient shall maintain patient-specific written or electronic records in accordance with Georgia law and the regulations of the Board of Pharmacy. If also providing patients with purchased drugs, the eligible recipient shall also note, either on the face of a written prescription or in the electronic record of prescription, that a donated drug was dispensed to the patient.
(13) An expiration date is required on all donated drugs dispensed. The expiration date shall be brought forward to the filled prescription. If multiple packaged donated drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date shall be used for the dispensed prescription.
(14) Dispensed drugs shall not expire before the use by the patient based on the prescribing practitioner's directions for use or, for over-the-counter medicine not dispensed pursuant to a prescription, the directions for use on the package's label.
(15) Dispensed drugs subject to a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. Section 355-1 shall be managed and dispensed according to the requirements of that strategy.

Authority: Code Sections 31-2A-6 and 31-8-304.

511-5-12-0.1-.07 Handling fees.

(1) 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 handling fee for each donated drug that is dispensed. Such a handling fee shall not exceed the reasonable costs of participating in the program including but not limited to the current and anticipated costs of educating eligible donors, providing technical support to participating

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donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies and equipment.

(2) Nothing in the preceding paragraph shall limit an eligible recipient from charging fees, including but not limited to a usual and customary charge, to donors, eligible recipients, health plans, pharmacy benefit managers, and other entities.

Authority: Code Sections 31-2A-6 and 31-8-304.