

WEST VIRGINIA CODE: §60B-1-5

§60B-1-5. Receipt, storage, and handling of donated drugs by an eligible recipient.

- (a) A donor may donate drugs to an eligible recipient.
- (b) An eligible recipient may receive, accept, donate, dispose, replenish, and store drugs that were either donated or repackaged as provided in subsection (f) of this section.
- (c) Prior to the first donation from a new donor, a recipient shall verify and record the following:
 - (1) The donor meets the definition of "donor" as provided in §60B-1-1 of this code;
 - (2) The donor's name, address, phone number, and license number if applicable;
 - (3) The donor shall only make donations of drugs in accordance with the program;
 - (4) The donor shall ensure 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
 - (5) If applicable, the donor shall 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.
- (d) An eligible recipient shall 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.
- (e) 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 provisions of the federal 340B Drug Pricing Program.
- (f) 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 authorized to dispense.
- (g) All donations received but not yet accepted into inventory shall be kept in a separate designated area.

(h) Prior to or upon accepting a donation into inventory, an eligible recipient shall maintain a written or electronic inventory of the donation, including:

- (1) The transaction date;
- (2) The name, strength, and quantity of each accepted drug; and
- (3) The name, address, and phone number of the donor.

(i) No record of a donation other than as described in subsection (h) of this section may be required.

(j) 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.

(k) 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.

(l) 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 board the identifier on requested records shall be replaced with the original information. An identifier may not be used on patient labels when dispensing or administering a drug.

(m) A drug wholesaler, distributor, supplier, or outsourcing facility registered pursuant to state law except reverse distributors, shall comply with the requirements of 21 U.S.C. §§ 360eee-1 - 360eee-4 relating to drug supply chain security. If a donation's transaction history is required, the record of transaction history begins with the donor of the drugs, shall include all prior donations, and, if the drug was previously dispensed, may not include drug information that is not otherwise required to be on the drug's label.