WEST VIRGINIA CODE: §60B-1-6

§60B-1-6. Dispensing and distribution of donated drugs.

(a) An eligible recipient may only dispense or administer prescription drugs if otherwise permitted by law.

(b) Donation and the brokering or other facilitation of a donation of a drug pursuant to this program may not be considered wholesale distribution and may not require licensure as a wholesaler.

(c) Donated prescription drugs may only be dispensed to eligible patients pursuant to a valid prescription drug order. 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.

(d) 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 the program unless both eligible recipients are under common ownership or common control.

(e) An eligible recipient shall dispose of any drug that does not meet all of the requirements of the program in one of the following ways:

(1) Return the drug to the donor;

(2) Destroy the drug through an incinerator licensed with the Environmental Protection Agency or other lawful method; or

(3) Transfer the drug to a reverse distributor.

(f) All such donated drugs to be disposed shall be quarantined in a separately designated area.

(g) An eligible recipient shall maintain a written or electronic record of disposal, including:

(1) The disposal method as described in subdivision (2), subsection (e) of this section;

(2) The date of disposal or quarantine; and

(3) The name, strength, and quantity of each drug disposed.

(h) No record of disposal other than as described in subsection (g) of this section may be required.

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(i) Donated drugs may not be resold and shall be considered nonsalable. However, reimbursement for any handling fee authorized pursuant to this chapter does not constitute reselling.

(j) Before dispensing a donated drug, an eligible recipient shall inspect the drug to determine that it has not adulterated. The drug shall be repackaged into a new container or all previous patient information and pharmacy labeling shall be redacted or removed from the donated container.

(k) Dispensed drugs shall clearly indicate the final dispensers information and current patient information, and shall be properly labeled in accordance with the regulations of the board.

(l) An eligible recipient that provides donated drugs to an eligible patient shall maintain patient-specific written or electronic records in accordance with West Virginia law and the rules of the board. 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.

(m) 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.

(n) Dispensed drugs may not expire before the use by the patient based on the prescribing practitioners directions for use or, for over-the-counter medicine not dispensed pursuant to a prescription, the directions for use on the packages label.

(o) Dispensed drugs subject to a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. §355-1 shall be managed and dispensed according to the requirements of that strategy.

(p) When complying with the provisions of this article and the rules and regulations adopted pursuant to this article, unless an action or omission constitutes willful or wanton misconduct, the following persons or entities shall not be subject to criminal or civil prosecution, criminal or civil liability for injury, death, or loss to person or property, other criminal or civil action, or disciplinary actions by licensing, professional, or regulatory agencies:

(1) A person that donates or gives drugs to an eligible recipient, including a drug wholesaler, drug manufacturer, reverse distributor pharmacy, third-party logistics provider, government entity, hospital, or health care facility;

(2) An eligible recipient;

(3) A health care professional who prescribes or dispenses a donated drug;

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(4) The Board of Pharmacy;

(5) An intermediary that helps administer the program by facilitating the donation or transfer of drugs to eligible recipients;

(6) A repackager or manufacturer of a donated drug; and

(7) Any employee, volunteer, trainee, or other staff of individuals and entities listed in subdivisions (1) through (6).

(q) An entity participating in a drug donation or repository program operated by another state may participate in this program, and in the case of a pharmacy, may dispense donated drugs to residents of this state. This entity is required to comply with all laws and rules in this state unless such laws or rules differ or conflict with the laws or rules of the state in which the entity is located.

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