WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Committee Substitute

for

House Bill 4387

BY DELEGATES GRAVES, PACK, ELLINGTON, KESSINGER,

SUMMERS, WAXMAN, LINVILLE, ROWAN, J. JEFFRIES,

HIGGINBOTHAM AND HILL

[Originating in the Committee on Health and Human

Resources; February 11, 2020.]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §60A-12-1, §60A-12-2, §60A-12-3, §60A-12-4, §60A-12-5, §60A-12-6, §60A-12-7 and §60A-12-8, all relating to creating the Donated Drug Repository Program; requiring the West Virginia Board of Pharmacy to administer the program; setting forth eligible drugs; setting forth eligible recipients; establishing how the drugs are to be received, handled, stored, dispensed, distributed, and disposed of; permitting a handling fee; defining terms; and permitting rulemaking.

Be it enacted by the Legislature of West Virginia:

CHAPTER 60B. DONATED DRUG REPOSITORY PROGRAM.

ARTICLE 1. DONATED DRUG REPOSITORY PROGRAM.

§60A-12-1. Definitions.

As used in this article:

"Board" means the West Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of §60A-2-1 *et seq.* of this code, and Schedules I through V of 21 CFR Part 1308.

"Donor" means 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 provider, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation center, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor also means 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.

"Drugs" means both prescription and non-prescription ("over-the-counter") drugs.

"Eligible patient" means an indigent person. However, if the recipient's supply of donated drugs exceeds the need for donated drugs by indigent persons, then any other person in need of a particular drug can be an eligible patient.

"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 that has been authorized by the West Virginia Board of Pharmacy.

"Healthcare facility" means a facility licensed by the State of West Virginia 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.

"Health care professional" means a person who is licensed by the State of West Virginia 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

"Indigent person" means a patient whose income is at or below the income eligibility requirements of the West Virginia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.

"Program" means the donated drug repository program established by rule pursuant to §60A-12-8 of this code.

"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.

§60A-12-2. Authority and waivers.

(a) A donor or eligible recipient may request a waiver or variance from the board with regard to any rule related to this program upon a showing it would be in the interest of public health and safety.

(b) The board has sole regulatory authority over the program.

(c) 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.

(d) An eligible recipient including, but not limited to, a pharmacy may receive drugs from a donor in accordance with the rules of this program.

(e) An eligible recipient may accept donated drugs that are in tamper-evident packaging, including, but not limited to, drugs that have a tamper-evident seal on either their immediate, outer, secondary, or shipping container.

(f) 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.

§60A-12-3. Eligible drugs.

(a) Drugs may only be dispensed pursuant to the program if:

(1) For prescription drugs, the prescription drug did 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

(2) 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.

(b) The following drugs may not be donated to the program:

(1) Controlled substances;

(2) Drugs subject to a federal Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. §355-1 if inventory transfer is prohibited by such strategy; or

(3) Drugs that there is reason to believe are adulterated.

§60A-12-4. Eligible recipients.

(a) 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 legally authorized to possess prescription drugs may become an eligible recipient for a period of one year by giving written notice to the board. That notice serves as authority for the recipient to participate in the program for a period of one year, unless revoked by the board. An eligible recipient may renew its authority by sending written notice in subsequent years.

(b) The board shall publish on its website the list of authorized recipients.

(c) An entity which chooses to participate in the program shall comply with this article and shall make all records available for audit by the board within five business days. Failure to comply with any provision of this article or statutes governing prescription drugs may result in revocation of authority to participate in the program. The 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.

§60A-12-5. 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 must verify and record the following:

(1) The donor meets the definition of "donor" as provided in §60A-12-1 of this code;

(2) The donor's name, address, phone number, and license number if applicable;

(3) The donor will only make donations of drugs in accordance with the program;

(4) The donor will 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 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.

(d) 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.

(e) A 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 article 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 article 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.

§60A-12-6. 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.

(i) Donated drugs may not be resold and shall be considered nonsalable. However, reimbursement for any handling fee authorized pursuant to this article 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 must be repackaged into a new container or all previous patient information and pharmacy labeling must be redacted or removed from the donated container.

(k) 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 board.

(l) An eligible recipient that provides donated drugs to an eligible patient shall maintain patient-specific written or electronic records in accordance with this article 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 practitioner's 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 manufacturer, wholesaler, 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;

(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 manufacturer or repackager 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.

§60A-12-7. Handling fees.

(a) An eligible recipient may not charge or collect any fees from an eligible patient for drugs dispensed pursuant to this program. However, an eligible recipient may charge a handling

fee for each donated drug that is dispensed. Such a handling fee may 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 donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies, and equipment.

(b) Nothing in the preceding subsection limits 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.

§60A-12-8. Rulemaking.

The board may propose rules for legislative approval in accordance with §29A-3-1 *et seq.* of this code to implement this article.

NOTE: The purpose of this bill is to create the Donated Drug Repository Program. The bill establishes the West Virginia Board of Pharmacy has the authority to administer the program. The bill sets forth eligible drugs and eligible recipients. The bill establishes how the drugs are to be received, handled, stored, dispensed, distributed, and disposed of. The bill permits a handling fee. The bill defines terms. The bill requires rule-making.

Strike-throughs indicate language that would be stricken from a heading or the present law, and underscoring indicates new language that would be added.