WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

7/29/2022 2:14:57 PM

Office of West Virginia
Secretary Of State

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Pharmacy TITLE-SERIES: 15-20

RULE TYPE: Legislative Amendment to Existing Rule: Repeal of existing rule:

RULE NAME: 15-20 Donated Drug Repository Program

PRIMARY CONTACT

NAME: Krista Capehart

ADDRESS: 2310 Kanawha Blvd E

Charleston, WV 25311

EMAIL: krista.d.capehart@wv.gov

PHONE NUMBER: 304-558-0558

CITE STATUTORY AUTHORITY: 60B-1

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

Board of Pharmacy to propose rules for the Donated Drug Repository Program §60B-1-8

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/29/2022

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/29/2022

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

Sets for the necessary requirements for the establishments and operation of a donated drug repository program in WV as required by HB 2817

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

0

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

0

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

0

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2022 Increase/Decrease (use "-")	2023 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

N/A

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Krista Capehart -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 20
DONATED DRUG REPOSITORY PROGRAM

§15-20-1 General

1.1 Scope. – To establish requirements and process for donated drug repository programs

1.2 Authority – W. Va. Code §60B-1

1.3 Filing Date

1.4 Effective Date

1.5 Sunset Date – This rule shall terminate and have no further force or effect on August 1, 2028.

§15-20-2 Definitions

2.1 The following words and phrases as used in this rule mean:

2.1.1 "Board" means the West Virginia Board of Pharmacy.

2.1.2 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.

2.1.3 "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.

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

2.1.5 ""Donated drug repository program" means a program authorized to accept prescription and non-prescription drugs donated or given for the purpose of being dispensed or personally furnished to individuals who are residents of this state and meets eligibility standards

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

2.1.7 "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.

2.1.8 "Healthcare facility" means a facility licensed by the State of West Virginia as a:

(1) Nursing home;

(2) Personal care home;

(3) Assisted living community;

(4) Residential care facility for the elderly;

(5) Hospice;

(6) Hospital;

(7) Home health agency; or

(8) A similar entity licensed in the state in which it is located.

2.1.9 "Health care professional" means a person who is licensed by the State of West Virginia to practice as a:

(1) Physician;

(2) Registered nurse or licensed practical nurse;

(3) Physician assistant;

(4) Dentist or dental hygienist;

(5) Optometrist; or

(6) Pharmacist.

2.1.10 "Indigent patient" 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.

2.1.11 "Program" means the donated drug repository program established by rule pursuant to §60B-1-8 of this code.

2.1.12 "Responsible individual" means a person permitted by law to have legal possession of prescription drugs.

2.1.13 "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.

§15-20-3 Waivers

3.1 A donor or eligible recipient may request a waiver from the board with regard to any rule related to this program by demonstrating the waiver is in the interest of public health and safety.

3.2 The donor or eligible recipient seeking the waiver will receive correspondence from the board with the decision.

§15-20-4 Authorization process for eligible recipients

4.1 To be eligible for participation in the program, 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 shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and all the appropriate licensure standards, and shall hold active, state-issued licenses or registrations in good standing.

4.2 An eligible recipient may establish a donated drug repository program at authorized address.

4.3 The eligible recipient shall provide written notification to the Board of participation in the program on the form provided.

4.4 Each eligible recipient shall make a separate notification to the board for each drug repository program address.

4.5 Each donated drug repository program must designate a responsible individual.

4.6 Each donated drug repository program notification shall be accompanied by a notification fee of $50 annually.

4.7 The notification shall serve for participation in the program for a period of one year, unless revoked by the Board. The eligible recipient may renew its authority via renotification annually by June 30.

4.8 Withdrawal from participation. A donated drug repository program may withdraw from the Program at any time by providing written notice to the Board on a form provided and available on the Board's website.

4.9 Failure to comply with any provision §60B-1, this Chapter, or statutes governing prescription drugs may result in revocation of authority to participate in the program. Revocation shall be provided as a written notice including the specific requirements that were violated and corrective actions necessary to reinstate its authority to participate in the program.

§15-20-5 Eligible Drugs

5.1 Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to a drug repository program if the drugs meet the requirements of this rule, as determined by the pharmacist or responsible healthcare provider of the drug repository program. The 18 year or older parent or guardian of a minor may donate the minor's legally obtained drugs or supplies if all requirements are met.

5.1.1 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.

5.2 No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopeia shall be donated or accepted as part of the donated drug repository program due to the increased potential for adulteration. Drugs donated directedly from a drug manufacturer, wholesaler, third party logistics provider, or pharmacy are excluded from this provision and may be donated.

5.3 Controlled substances shall not be donated or accepted.

5.4 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 may not be donated or accepted.

5.5 Drugs may be dispensed by a donated drug repository program only if all of the following are met:

5.5.1 The drug is in unopened, tamper-evident packaging as defined by the United States Pharmacopeia General Chapter 659, Packaging and Storage Requirements, including but not limited to unopened, unit-dose and multiple dose packaging. A drug in a single-unit dose or blister pack with the outside packaging opened may be dispensed if the single unit-dose packaging is undisturbed and meets the labeling requirements of §15-1-20.2.1;

5.5.2 The drug has been stored according to manufacturer's or USP storage conditions;

5.5.3 The packaging contains the expiration date;

5.5.4 The drug has an expiration date that is more than six months after the date that the drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and dispensed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;

5.5.5 The drug does not have any physical signs of tampering or adulteration, and there is no reason the believe that the drug is adulterated;

5.5.6 The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration; and

5.6 A drop box may not be used to deliver or accept donations.

§15-20-6 Storage and handling of donated drugs by eligible recipients

6.1 A licensed pharmacist or the responsible healthcare professional for the donated drug repository program shall inspect the donated drugs prior to dispensing to determine, to the extent reasonable possible in their professional judgement, that the drugs are not adulterated or misbranded, are safe and suitable for dispensing.

6.2 The eligible recipient shall store and maintain donated drugs in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeia Standards.

6.3 If a recall notification is received, the donated drug repository program shall identify all recalled prescription product in the facility, dispose of all recalled drug as directed in the recall, and document the disposal in the records for the donated drug repository program. If a recalled drug has been dispensed, the donated drug repository program shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

§15-20-7 Eligible Patients

7.1 An individual must meet the following criteria to be eligible to receive medication from a donated drug repository:

7.1.1 Income is at or below the income eligibility requirements of the West Virginia Medicaid Program;

7.1.2 Uninsured;

7.1.3 Underinsured; or

7.1.4 Enrolled in a public assistance health benefits program.

7.2 If a donated drug repository program's supply of donated drugs exceeds the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.

§15-20-8 Dispensing of donated drugs

8.1 Donated drugs may be dispensed only be dispensed to eligible patients pursuant to a valid prescription order.

8.2 A donated drug repository program shall dispense donated prescription drugs in compliance with federal and state laws and regulations for dispensing prescription drugs, including but not limited to all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling. The eligible patient will be counseled and sign an acknowledgement that the drug was donated.

8.3 Donated drugs may not be resold and shall be considered nonsalable. However, reimbursement for any handling fee does not constitute reselling. A donated drug repository program may charge the eligible recipient a handling fee not to 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.

8.4 The fees charged, and costs listed in §15-20-8.3 shall be included in the audit information made available to the Board.

8.5 Nothing in the preceding paragraph 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.

§15-20-9 Required Records

9.1 Prior to upon accepting a donation into inventory, a donated drug repository program that dispenses

donated drugs or supplies to an eligible patient shall maintain a written or electronic inventory of each donated drug or supply that shall include the following information:

9.1.1 The transaction date;

9.1.2 The name, strength, and quantity of each accepted drug; and

9.1.3 The name, address, and phone number of the eligible donor providing each drug or supply.

9.2 A donated drug repository program 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 person. Replenishment shall follow applicable provisions of the federal 340B Drug Pricing Program. Replenishment may not be done using drugs donated by the public.

9.3 In addition to all records required for dispensing a prescription drug or supply under §30-5 and rules, a donated drug repository program 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 if the site dispenses both donated and non-donated drugs.

9.4 All records must be made available for audit by the Board within five business days.

9.5 All records must be kept for six years.

9.6 Prior to the first donation from a new donor, an eligible recipient shall collect an attestation signed electronically or physically by the person making the donation or that person's authorized representative, verifying and recording information required by §60B-1-5(c).

§15-20-10 Exemption from disciplinary action, civil liability or criminal prosecution

10.1 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 from injury, death, or loss to person or property, or other criminal or civil action, or disciplinary actions by licensing, professional, or regulatory agencies:

10.1.1 A person who 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 entity;

10.1.2 An eligible recipient;

10.1.3 A healthcare professional who prescribes or dispenses a donated drug;

10.1.4 The Board of Pharmacy;

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

10.1.6 A repackager or manufacturer of a donated drug; and

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