

- Section 5.2:** Recommend provision for receiving pharmacy to determine if they can confirm appropriate medication storage to accept non-room temperature medication (e.g., patient’s home medication stored at hospital pharmacy during inpatient admission).
Response: The Board appreciates the intent of the comment. However, in the provided example the receiving pharmacy is unable to ascertain the storage conditions of the non-room temperature medications while the patient’s medication was at the patient’s home prior to the inpatient admission. Therefore, the Board has elected to not make any modification to the rule based on this comment.
- Section 5.5.4:** Recommend simplifying rule to state that the expiration date is no later than the soonest patient dispensation and fill completion is expected to occur. The dispensing pharmacy would be able to institute more restrictive rules such as a 3/6/9-month expiration window if desired on a local level. Current language making an exception for drugs in “high demand” is unclear as to what qualifies as high demand.
Response: The Board appreciates the comment but feels for patient safety a boundary needs to be placed in regulations. The Board views that “high demand” could be interpreted by the professional judgment of the pharmacist as one that is highly sought after due to cost, limited availability, the condition it treats, etc. Therefore, the Board sees this as less restrictive language rather than more restrictive language giving the program flexibility within their professional judgment to accept the product if it truly is a special need. Regarding the suggestion, the Board has elected to not make any additional modifications to the proposed rule based on this comment.
- Section 7.1:** Clarify if records must be kept demonstrating patient receiving donated drug meets the definition of an eligible patient.
Response: It is the responsibility of the donated drug repository to ensure that both the patient meets eligibility requirements in both statute and rule. The supply may only be used for patients that do not meet the eligibility criteria if supply exceeds demand by those eligible or indigent patients. This would be up to the eligible recipient how this is done to ensure compliance with the statute and rule.
- Section 9.2: Clarification Requested:** Clarify if intent of current language is to limit replenishment to only drug stock donated by entities legally authorized to possess drugs with a license or permit and excludes drug stock donated by an individual member of the public.
Response: As the Board understands the intent from the legislature in §60B-1-6(f), if the patient is receiving both donated and purchased drug from the eligible recipient that the eligible recipient shall 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.” Thus, the Board views this to preclude the use of drug stock donated from an individual member of the public from use for replenishment.

Commenter 2: George Wang, PhD

Date Received: July 28, 2022

Co-Founder and Director of SIRUM

- Comment 1:** We recommend amending the proposed rules with respect to inventory record requirements to be consistent with statute and reduce unnecessary and duplicative recordkeeping burdens. Section 60B-1-5(h) states that prior to accepting a donation into inventory, an eligible recipient must maintain a written or electronic inventory of the donation, which includes (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. Pursuant to §60B-1-5(i), no record of donation other than described in subsection (h) may be required.

Response 1: The Board appreciates this recommendation. WV regulation §15-1-20.2 requires a lot number on all unit dose, unit of use, punch card packaging when utilized for “controlled administration of drugs, for oral administration, to ambulatory patients, and to patients and residents of health institutions.” However, given §60B-1-5(h), the Board recognizes it cannot be included have modified Subdivision 15-20-5.5.7 by moving it to 15-20-9.1 and changing as below:

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.

And

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).

- **Comment 2/3:** We suggest removing the patient acknowledgement requirement in Section 8.2, as Section 9.3 requires the donation to be noted on either the face of the written prescription or in the electronic record. 3. If #2 is not accepted, then we strongly support amending section 8.2, requiring that the patient be informed that the donated stock may be dispensed.

Proposed response: The notation required in Section 9.3 refers to the documentation that a donated drug was dispensed, not that a patient is recognizing they received a donated drug. These are two different types of documentation. The Board believes it is necessary that the patient acknowledge the receipt of donated drug and have elected to not make any modifications to the proposed rule based on this comment.

- **Comment 4:** To be consistent with the statute provisions, we recommend removing manufacturer's lot number requirements and implementing additional recall rules to maintain the same level of safety and increase the amount of drugs eligible for donation. **Proposed response:** See response to Comment 1. Additionally, the Board will make the same modification to 15-20-5.5.3. and adding 15-20-6-4
5.5.3 The packaging contains the expiration date;

15-20-6. Drugs specified in a recall notice shall be considered recalled unless the drug has an affected lot number to exclude it from the recall.

- **Comment 5: Some important drugs are excluded by not allowing for the donation of drugs that require storage temperatures other than normal room temperature. We suggest allowing the option for temperature-controlled drugs to be donated by more donors with additional stipulations.**

Proposed Response 5: The Board notes that several of the additional entities listed in the suggested language in the comment including: repacker, relabeler, Veterans Affairs hospital are included in the Board’s definition of pharmacy, wholesale drug distributor, or manufacturer. Regarding the other suggestions, the Board has elected to not make any additional modifications to the proposed rule based on this comment due to patient safety concerns.

- **Comment 6: The current rules could be interpreted to require every donated drug be inspected by a pharmacist or the responsible healthcare professional. We suggest requiring donated drugs being inspected prior to dispensing like the statute.**

Proposed Response 6: The Board believes the intent of the is that every drug must be inspected by a pharmacist prior to dispensing by a pharmacist or the responsible healthcare professional. To provide additional clarity the Board has modified Subsections §15-5-5, §15-5-5.1 and §15-6-1

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;

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.

- **Comment 7:** Permit eligible recipients to charge a flexible handling fee to cover reasonable costs for redistributing donated drugs.

Proposed Response 7: The Board appreciates the comment and recognizes the need a financially viable program while maintaining the integrity of the program itself. The Board proposes to modify the Subsections below:

§15-20-8.3_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 audited 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.

- **Comment 8/9:** We strongly support rules providing participating providers discretion for the expiration date cutoff of donated drugs. We suggest simplifying the draft rules to specify donated drugs must not be expired to avoid inventory shortages.

Proposed Response 8/9: It is important to recognize that the Board’s role is to not simply restate the statute but provide additional safety boundaries necessary for the program as directed by the WV Legislature. The Board appreciates the comment but feels for patient safety a boundary needs

to be placed in regulations for medication expiration date. The Board views that “high demand” could be interpreted by the professional judgment of the pharmacist as one that is highly sought after due to cost, limited availability, the condition it treats, etc. Therefore, the Board sees this as less restrictive language rather than more restrictive language giving the program flexibility within their professional judgment to accept the product if it truly is a special need. Regarding the suggestion, the Board has elected to not make any additional modifications to the proposed rule based on this comment.

- **Comment 10:** We suggest incorporating additional statutory provisions into the draft rules for consistency and clarification purposes.

Proposed Response 10: The Board thanks you for your comment but utilizes rules to clarify and articulate statute rather than simply restating statute. Therefore, the Board has elected to not make any additional modifications to the proposed rule based on this comment.

CONCLUSION

The Board’s filing of the proposed rule has incorporated several comments from stakeholders after careful consideration of the Board to clarify and the rule. The Board appreciates the written comments and participation in the process.

BOARD MEMBERS

*John J. Bernabei
James Rucker *
Jenna Misiti *
Sam Kapourales
David Bowyer
Dennis Lewis
Vicky Skaff
(*Public Member)*



STAFF

*Michael L. Goff,
Executive Director &
CSMP Administrator*

*John Smolder,
CFO/COO*

*Krista D. Capehart, Dir. Of
Professional & Regulatory
Affairs*

*Office Address
2310 Kanawha Blvd, East
Charleston, WV 25311*

www.wvbp.com

*Phone
(304) 558-0558
(304) 558-0572 (fax)*

July 29, 2022

Ashley Street, PharmD, MSHA
Assistant Director of Pharmacy, Adult Clinical Services & Education
WVU Medicine – WVU Hospitals
ashley.street@wvumedicine.org

Dear Dr. Street:

The West Virginia Board of Pharmacy thanks you for taking the time to provide comments on the Board's proposed rule 15 CSR 20 Donated Drug Repository Program.

The Board has met and carefully considered all of the comments received. Several modifications to the proposed rule have been made based on the comments received. Enclosed please find the *Summary of Comments Received Regarding Proposed Rule for 15 CSR 20 and Responses of the WV Board of Pharmacy*.

The agency-approved proposed rule will be filed today with the West Virginia Secretary of State's office. Both the proposed rule and comments in their entirety can be viewed there. Thank you for your time and participation in the rule-making process.

Professionally,

Krista Capehart, PharmD, MS, BCACP, FAPhA

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*Office Address
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www.wvbp.com

*Phone
(304) 558-0558
(304) 558-0572 (fax)*

July 29, 2022

George Wang, PhD
Co-founder and Director
SIRUM
Via Sara DiBernardo, Esq.
sara@sirum.org

Dear Dr. Wang:

The West Virginia Board of Pharmacy thanks you for taking the time to provide comments on the Board's proposed rule 15 CSR 20 Donated Drug Repository Program.

The Board has met and carefully considered all of the comments received. Several modifications to the proposed rule have been made based on the comments received. Enclosed please find the *Summary of Comments Received Regarding Proposed Rule for 15 CSR 20 and Responses of the WV Board of Pharmacy*.

The agency-approved proposed rule will be filed today with the West Virginia Secretary of State's office. Both the proposed rule and comments in their entirety can be viewed there. Thank you for your time and participation in the rule-making process.

Professionally,

Krista Capehart, PharmD, MS, BCACP, FAPhA

Pharmacy Department
PO Box 8045
One Medical Center Drive
Morgantown, WV 26506-8045
Phone / 304-598-4148
Fax / 304-598-4073

July 26th, 2022

Krista Capehart, PharmD
West Virginia Board of Pharmacy
2310 Kanawha Blvd E
Charleston, WV, 25311

Re: Proposed legislative rule for Donated Drug Repository Program, title-series 15-20, statutory authority W. Va. Code §60B-1.

Dear Dr. Capehart,

The Pharmacy Enterprise of WVU Medicine is pleased to submit comments regarding the proposed legislative rules for the Donated Drug Repository Program. The Pharmacy Enterprise comprises pharmacy departments from 14 West Virginia-based member hospitals of the WVU Health System and is led by Chief Pharmacy Officer Todd Karpinski, PharmD. The WVU Medicine Pharmacy Enterprise thanks the West Virginia Board of Pharmacy for the opportunity to comment on the proposed rule. We hope that our feedback will assist you in refining these rules to meet our shared patient care and quality goals.

- **Section 4.6:** Recommend biennial registration rather than annual to align with current schedule for pharmacy permits and mail-order permits. Consider linking re-registration to schedule for renewal of pharmacy permits.
- **Section 5.1: *Clarification Requested:*** Does current language explicitly allow individual public donors to donate drugs prescribed to someone else, e.g., a parent? Can a health care provider donate drugs prescribed to a patient under their care? Recommend stating that parents/guardians who are 18 years of age or older may donate drugs prescribed to minors if the drugs meet all requirements.
- **Section 5.2:** Recommend provision for receiving pharmacy to determine if they can confirm appropriate medication storage to accept non-room temperature medication (e.g., patient's home medication stored at hospital pharmacy during inpatient admission).
- **Section 5.5.4:** Recommend simplifying rule to state that the expiration date is no later than the soonest patient dispensation and fill completion is expected to occur. The dispensing pharmacy would be able to institute more restrictive rules such as a 3/6/9-month expiration window if desired on a local level. Current language making an exception for drugs in "high demand" is unclear as to what qualifies as high demand.
- **Section 7.1:** Clarify if records must be kept demonstrating patient receiving donated drug meets the definition of an eligible patient.
- **Section 9.2: *Clarification Requested:*** Clarify if intent of current language is to limit replenishment to only drug stock donated by entities legally authorized to possess drugs with a license or permit and excludes drug stock donated by an individual member of the public.

We appreciate the opportunity to offer our input and suggestions on the proposed rule. If we can provide further information or assist the agency in any way, please do not hesitate to contact me at 304-548-4148 extension 73352 or ashley.street@wvumedicine.org.

Sincerely,

Ashley Street, PharmD, MSHA
Assistant Director of Pharmacy, Adult Clinical Services & Education
WVU Medicine – WVU Hospitals



July 28, 2022

Dr. Krista Capehart
2310 Kanawha Blvd E
Charleston, West Virginia 25311
Krista.d.capehart@wv.gov

**RE: Comments on West Virginia Board of Pharmacy Legislative Proposed Rule 15-20
Donated Drug Repository Program**

Dear Dr. Capehart:

We are writing to comment on the proposed rules for the Donated Drug Repository Program filed on June 28, 2022, as published in the *West Virginia Register*. Thank you for the opportunity to submit these comments. Please let us know if we can further clarify anything or provide any additional information.

About SIRUM

SIRUM is a 501(c)3 nonprofit, founded at Stanford University that helps implement state-based programs to donate unused medications to patients in need. Donated medication is often the safety-net's last line of defense for vulnerable patients. We currently help operate donation programs in eight states, helping tens of thousands of patients access millions of dollars of donated medication that they would not otherwise have been able to afford or access.

Comments and Considerations

We believe that the Donated Drug Repository Program has an enormous potential to reduce health care costs and reduce needless waste for West Virginia and West Virginians and we are overall very supportive of the regulation. Based on our experience operating drug donation





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programs, we have outlined some concerns and considerations below. Most importantly some of the suggested language appears to conflict with statute. In these cases, we have suggested amendments that try to achieve the same goals while remaining consistent with the statute's wording and intentions.

In addition to our written comments, we have also provided a supplement which incorporates our recommended amendments to the draft rules for your consideration and convenience.

Sincerely,

George Wang, PhD
Co-Founder & Director

SIRUM | Saving Medicine. Saving Lives.





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Comments for Proposed Rule

- 1. We recommend amending the proposed rules with respect to inventory record requirements to be consistent with statute and reduce unnecessary and duplicative recordkeeping burdens.**

Section 60B-1-5(h) states that prior to accepting a donation into inventory, an eligible recipient must maintain a written or electronic inventory of the donation, which includes (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. Pursuant to §60B-1-5(i), no record of donation other than described in subsection (h) may be required.

As currently written, subsection 5.5.7 of the proposed rules imposes inventory record requirements that are inconsistent with the statute. We believe the inventory requirements set forth in subsection 5.5.7 would be better suited in section 15-20-9, which sets forth the recordkeeping requirements for the donated drug repository program.

Additionally, to ensure uniformity and transparency with recordkeeping, we recommend amending subsection 9.1 to reflect the requirements prescribed in statute.

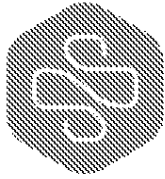
Lastly, we suggest shifting the signature requirement from 5.5.7 to new donors, prior to their first donation, acknowledging they meet the donor eligibility requirements pursuant to §60B-1-5(c).

Based on the reasons detailed above, we suggest amending the proposed rules as follows:

§15-20-5 Eligible Drugs

~~5.5.7 All drugs shall be inventoried at the donated drug repository program and shall include the name, strength, dosage form, quantity, lot number and expiration date of the drug. If the drug has not been continually under the control of a health care~~





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~~professional or drug manufacturer, distributor, or third party logistics entity, the donated drug repository program shall collect a donation form that is signed by the person making the donation or that person's authorized representative.~~

§15-20-9 Required Records

9.1 **Prior to or upon accepting a donation into inventory.** ~~A~~ **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.~~12~~ The name, strength, ~~dosage forms,~~ **and** quantity, ~~manufacturer's lot number, and expiration date~~ **of each accepted drug; and**

9.1.~~23~~ The name, address, and phone number **of** the eligible donor providing each drug or supply.

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 pursuant to West Virginia Code §60B-1-5(c).

2. We suggest removing the patient acknowledgement requirement in Section 8.2, as Section 9.3 requires the donation to be noted on either the face of the written prescription or in the electronic record.

We recommend removing the provision requiring eligible patients to sign an acknowledgement that the drug was donated, as this is recorded on either the face of the prescription or in the





electronic record. We believe this will reduce the paperwork burden while maintaining the same level of accountability and transparency. We suggest the following amendment to the rules:

§15-20-8 Dispensing of donated drugs

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.~~

- 3. If #2 is not accepted, then we strongly support amending section 8.2, requiring that the patient be informed that the donated stock may be dispensed.**

This comment is interrelated to comment #2 above, and if the suggestion in comment #2 is accepted, then this comment can be disregarded. However, if the suggestion in comment #2 is not accepted, we separately ask that section 8.2 be amended to require eligible patients be informed that the dispensing entity may dispense donated stock.

We suggest the following amendment to the proposed rules:

§15-20-8 Dispensing of donated drugs

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. **At the time of or prior to the first dispensing of donated medications to a new eligible patient, the patient will be counseled and sign an acknowledgement that the drug was donated shall be informed that the medications were donated.**





4. **To be consistent with the statute provisions, we recommend removing manufacturer’s lot number requirements and implementing additional recall rules to maintain the same level of safety and increase the amount of drugs eligible for donation.**

As currently drafted, eligible recipients may only accept drugs into inventory that contain a lot number. We have seen in many states this requirement preclude a significant number of otherwise eligible drugs from the long-term care sector from donation. We suggest allowing medicine to be donated without lot numbers and the addition of instructions to include drugs without a lot number that are subject to a recall along with the affected lot numbers. This is the case for almost all operational donation programs in the country.¹ Additionally, the statute intentionally omits the requirement for lot numbers on drugs to be eligible for donation or dispensing. For these reasons above and for consistency with the statutory provision §60B-1-5(i) that preclude any record of donation other than described in subsection §60B-1-5(h), we suggest the following amendments:

§15-20-5 Eligible Drugs

5.5.3 The packaging contains the ~~lot number and~~ expiration date;

5.5.7 All drugs shall be inventoried at the donated drug repository program and shall include the name, strength, dosage form, quantity, ~~lot number~~ and expiration date of the drug. If the drug has not been continually under the control of a health care professional or drug manufacturer, distributor, or third-party logistics entity, the donated

¹Some examples include the following: Oklahoma: [535:12-1-10 \(7\)](#) If a drug is recalled and the eligible pharmacy does not have the lot number on the label to differentiate between the recall and non-recalled, all such donated recalled drug shall be destroyed. Iowa: [109.4\(4\)c](#). If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall, pursuant to Iowa board of pharmacy rules. Wyoming: [Section 9 \(b\)](#) If a medication is recalled and the eligible Participating Donation Site does not have the lot number on the label to differentiate between the recall and nonrecalled, all such donated medications shall be destroyed and documented using standard procedures.





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drug repository program shall collect a donation form that is signed by the person making the donation or that person's authorized representative.

The recommended amendment in the paragraph immediately preceding this paragraph is interrelated to comment #1. If the suggestion in comment #1 is accepted, then the recommendation to remove lot number from subsection 5.5.7 can be disregarded. However, if the suggestion in comment #1 is not accepted, we separately ask that the lot number requirement be struck from subsection 5.5.7.

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

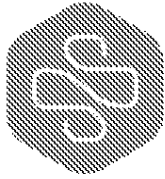
6.4 Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number to exclude it from the recall.

§15-20-9 Required Records

9.1.2 The name, strength, dosage forms, quantity, ~~manufacturer's lot number,~~ and expiration date.

The recommended amendment in the paragraph immediately preceding this paragraph is interrelated to comment #1. If the suggestion in comment #1 is accepted, then the recommendation to remove lot number from subsection 9.1.2 can be disregarded. However, if the suggestion in comment #1 is not accepted, we separately ask that the lot number requirement be struck from subsection 9.1.2.





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5. Some important drugs are excluded by not allowing for the donation of drugs that require storage temperatures other than normal room temperature. We suggest allowing the option for temperature-controlled drugs to be donated by more donors with additional stipulations.

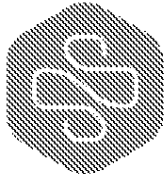
Some of the most valuable and important medications for underserved populations are temperature sensitive such as insulin. We agree that temperature-sensitive drugs need to be handled carefully to ensure their safety and ask that the rules allow for the donation of temperature-sensitive drugs so long as the proper temperature control can be verifiably maintained during transit.

We suggest the following changes to the proposed rules:

§15-20-5 Eligible Drugs

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, **unless the drugs are** ~~Drugs~~ donated directly from a drug manufacturer, wholesaler, third party logistics provider, ~~or~~ pharmacy, **dispenser, clinic, prescriber or other health care professional, health care facility, repackager, relabeler, Veteran Affairs hospital, prison or an entity participating in a drug donation or repository program pursuant to another state's law** ~~are excluded from this provision and may be donated~~ **or the donor has ensured the integrity of the drug by enclosing in the donation packaging a USP-recognized method by which the eligible recipient can easily detect improper temperature variations.**





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6. **The current rules could be interpreted to require every donated drug be inspected by a pharmacist or the responsible healthcare professional. We suggest requiring donated drugs being inspected prior to dispensing like the statute.**

In some instances, drugs could be donated to a participating recipient that are not needed or not on the provider's formulary. To help in these cases, drug donation programs typically have non-pharmacist staff that help sort out drugs that will never be dispensed. Additionally, subsections 5.5 and 6.1 of the rules, as currently written, are inconsistent with the statute, which intentionally requires an eligible recipient to inspect a drug prior to dispensing. We suggest the following edits to clarify that drugs that will not be used by the repository do not need to be inspected by a pharmacist.

§15-20-5 Eligible Drugs

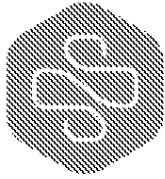
5.5 Drugs may be ~~accepted~~ **dispensed** by a donated drug repository program only if all of the following are met;

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 ~~accepted~~ **dispensed** if the single unit-dose packaging is undisturbed and meets the labeling requirements of §15-1-20.2.1;

§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.





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7. Permit eligible recipients to charge a flexible handling fee to cover reasonable costs for redistributing donated drugs.

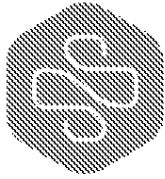
With regard to fees that an eligible recipient may charge, we strongly support flexibility and recommend against a cap because a primary issue with donation programs today is financial viability. Donation programs that lack adequate sources of funding, especially those without state funding, are often unsuccessful or become nonoperational. Allowing eligible recipients to charge a flexible handling fee is necessary to support the continued financial viability—and success—of donation programs. We believe an ideal model is the Georgia donation program handling fee rule 511-5-12-.07, which ties the fees charged to the “reasonable costs of participating in the program.” This approach provides the flexibility needed to address the concerns listed above and does not include a cap, which does not account for the high cost of handling some drugs (e.g. temperature-sensitive drugs). For the reasons above, we suggest the following amendment in line with the statute:

§15-20-8 Dispensing of donated drugs

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 ~~100~~ percent of the ~~West Virginia professional dispensing fee §33-51-9(f)~~ plus a shipping fee, if required, not to exceed 100 percent of the same ~~West Virginia Medicaid professional dispensing fee~~ **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 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.





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8. We strongly support rules providing participating providers discretion for the expiration date cutoff of donated drugs. We suggest simplifying the draft rules to specify donated drugs must not be expired to avoid inventory shortages.

We believe -- other than not being expired -- an expiration date limit is best left between the authorized recipient and the donor and does not need to be outlined in rules. Subsection 5.5.4 of the proposed rules, requires a drug to have an expiration date that is more than six months after the date that the drug was donated. To remain consistent with statutory requirements and provide uniformity in operations, we suggest amending the proposed rules to require that a drug must be expired to be accepted into inventory.

Additionally, we suggest amending the dispensing rules set forth in section 15-20-8, to require that a drug may only be dispensed if it will not expire before the completion by the eligible patient based on the prescribing health care professional's directions for use. Allowing health care professionals to use their professional judgment will maintain the same level of safety while increasing the stock of donated drugs available to those eligible patients in need.

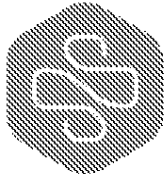
Further, we believe the exception for "high demand" drugs is restrictive, because it may preclude many "high value" drugs from donation that many eligible patients may not have access to otherwise.

For the reasons set forth above, we suggest the following amendments:

§15-20-5 Eligible Drugs

5.5.4 The drug has ***not expired*** ~~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;~~





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§15-20-8 Dispensing of donated drugs

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

8.1.1 Drugs may only be dispensed if they will 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, will not expire before use by the eligible patient based on the directions for use on the manufacturer's label.

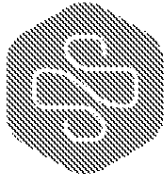
9. If comment #8 is not accepted, then we strongly support amending the rules to require an expiration date of more than three months after the date the drug was donated.

This comment is interrelated with comment #8 above, and if the suggestions in comment #8 are accepted, then this comment can be disregarded. However, if the suggestions in comment #9 are not accepted, we separately ask that the expiration date cut off be reduced to three months after the date of donation. We believe a six month limitation on expiration dates will diminish the donation inventory stock of otherwise eligible drugs. Moreover, the exception for "high demand" drugs is restrictive, because it may preclude many "high value" drugs from donation that many eligible patients may not have access to otherwise.

§15-20-5 Eligible Drugs

5.5.4 The drug has an expiration date that is more than **three** ~~six~~ months after the date that the drug was donated. ~~However, a donated prescription drug bearing an expiration date that is **three** 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;~~





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10. We suggest incorporating additional statutory provisions into the draft rules for consistency and clarification purposes.

Based on our experiences with other state programs, we have found that the success of programs is bolstered by consistent and complementary statutory and regulatory requirements. We recommend incorporating the following statutory provisions into the draft rules to support the development and operation of the drug donation program.

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

6.5 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:

6.5.1 Return the drug to the donor;

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

6.5.3 Transfer the drug to a reverse distributor.

6.6. An eligible recipient shall maintain a written or electronic record of disposal, including:

6.6.1 the disposal method as described in subdivision 6.5;

6.6.2 the date of disposal or quarantine; and

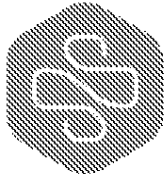
6.6.3 the name, strength, and quantity of each drug disposed

6.7. No record of disposal other than as described in subsection 6.6 of this section may be required

6.8 All such donated drugs to be disposed shall be quarantined in a separately designated area.

6.9 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





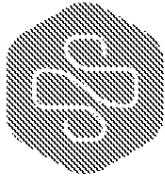
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and rules in this state unless such laws or rules differ or conflict with the laws or rules of the state in which the entity is located.

6.10 Drugs may be repackaged as necessary for storage, replenishment, dispensing, administration, 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.

6.11 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.





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15CSR20

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





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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

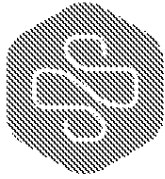
2.1.6 “Eligible patient” means an indigent person. However, if the recipient’s supply of donated drugs exceeds the need for donated drugs by indigent patients, then any other person in need of a particular drug can be an eligible patient.

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;





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(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.

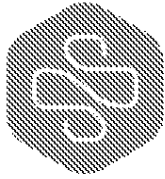
2.1.10 “Indigent patient” means a patient whose income is at or below the income eligibility requirements of the West Virginia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.

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





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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.

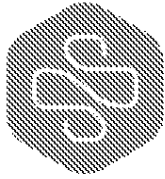
4.3 The eligible recipient shall provide written notification to the Board of participation in the program on the form provided.

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.





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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

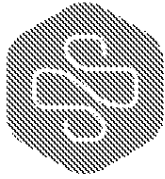
5.1 Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to a drug repository program if the drugs meet the requirements of this rule, as determined by the pharmacist or responsible healthcare provider of the drug repository program.

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, *unless the drugs are* donated directly from a drug manufacturer, wholesaler, third party logistics provider, *pharmacy, dispenser, clinic, prescriber or other health care professional, health care facility, repackager, relabeler, Veteran Affairs hospital, prison or an entity participating in a drug donation or repository program pursuant to another state's law* or the donor has ensured the integrity of the drug by enclosing in the donation packaging a USP-recognized method by which the eligible recipient can easily detect improper temperature variations.

5.3 Controlled substances shall not be donated or accepted.





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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 ~~received~~ *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 ~~received~~ *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 ~~lot number and~~ expiration date;

5.5.4 The drug has *not expired* ~~the expiration date is not past the expiration date and the drug is not expired.~~

5.5.5 The drug does not have any physical signs of tampering or adulteration, and there is no reason to 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

~~.....~~





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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.

6.4 Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number to exclude it from the recall.

6.5 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:

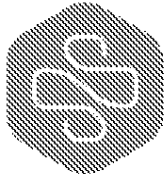
6.5.1 Return the drug to the donor;

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

6.5.3 Transfer the drug to a reverse distributor.

6.6. An eligible recipient shall maintain a written or electronic record of disposal, including:





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6.6.1 the disposal method as described in subdivision 6.5;

6.6.2 the date of disposal or quarantine; and

6.6.3 the name, strength, and quantity of each drug disposed.

6.7. No record of disposal other than as described in subsection 6.6 of this section may be required

6.8 All such donated drugs to be disposed shall be quarantined in a separately designated area.

6.9 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.

6.10 Drugs may be repackaged as necessary for storage, replenishment, dispensing, administration, 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.

6.11 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.

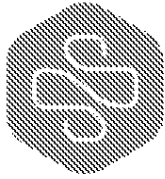
§15-20-7 Eligible Patients

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;





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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

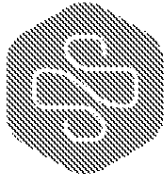
8.1 Donated drugs may be dispensed only be dispensed to eligible patients pursuant to a valid prescription order.

8.1.1 Drugs may only be dispensed if they will 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, will not expire before use by the eligible patient based on the directions for use on the manufacturer's label.

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.

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.**





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8.4 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 or 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:

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 five years.





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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 pursuant to West Virginia Code §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)

