Comments on Administrative Rules for Pharmacy-Program for Utilization of Unused Prescription Drugs
Rule Set 2022-62 LR
Rose Baran Pharm. D.
May 7, 2024

Rule	Issue	Suggested Change
338.3607(2)		
338.3607(2) Controlled substances submitted for donation ~~shall~~ **must** be documented and returned immediately to the eligible facility that donated the drugs. Both of the following apply: (a) If controlled substances enter the participating pharmacy or charitable clinic and it is not possible or practicable to return the controlled substances to the donating facility, abandoned controlled substances ~~shall~~ **must** be documented and destroyed ~~pursuant to~~ **under** the protocols currently used by the **participating** pharmacy.	A pharmacy must follow the DEA regulations for destruction of controlled substances. As curtainly written it would violate the Secure and Responsible Drug Act of 2010.	Delete 338.3607(2) as rule 338.3607(1) already states-controlled substances must not be accepted under the program.
Rule 338.3609		
R 338.3609 **Standards and procedures for inspecting** ~~Donated~~ **donated** prescription drugs; participating pharmacy or charitable clinic requirements. Rule 9. (1) A participating pharmacy or charitable clinic may accept a prescription drug only if all of the following requirements are met: (a) The drug is in its original sealed and tamper-evident packaging. However,	21 CFR 201.18 requires a lot number on prescription drugs. "The lot number on the label of a drug should be capable of yielding the complete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded." In February 2023 and in February 2024 the department gave a presentation to the Board indicating one of the common pharmacy violations found was 338.589(1) for	Change (c) to read: The drug package contains the information required by the Food Drug and Cosmetic Act and the transaction information required by the Drug Quality Security Act when a drug is transferred to the participating pharmacy or the charitable clinic pharmacy.

a drug in a single-unit dose, unit of issue package, or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging or unit of issue packaging is unopened. (b) The drug has been stored according to manufacturer or ~~usp-nf~~ **USP-NF** storage requirements. (c) The packaging contains the ~~lot number and~~ expiration date of the drug **and the lot number if the donation is received from an outsourcing facility.** If the lot number is not retrievable, all specified medications ~~shall~~ **must** be destroyed ~~in the event of~~ **if there is** a recall. (d) The drug **is not expired.** ~~has an expiration date that is more than 6 months after the date that the drug was donated.~~ (e) The drug does not have ~~any~~ physical signs of tampering**,** ~~or~~ adulteration, **or misbranding** and there is no reason to believe that the drug is adulterated **or misbranded**. (f) The packaging does not have ~~any~~ physical signs of tampering, deterioration, compromised integrity, **misbranding,** or adulteration.	unlabeled or incorrectly labeled medications, i.e. lacking a lot number. Lacking a lot number would make the drug misbranded. Misbranding under 21 USC 352 of the Federal Food, Drug and Cosmetic Act "Its labeling is false or misleading in any particular." Effective November 27, 2023, pharmacies must comply with the Drug Supply Chain Security Act, Public Law 113-54. The law requires the lot number of the drug along with other information be transferred to the pharmacy receiving the drug. No lot number would cause the product to be misbranded. Pharmacies may not dispense misbranded drugs, MCL 333.17764.	
Rule 338.3617(8)		
(8) Notwithstanding any federal or state law, or rule to the contrary, a participating pharmacy may repackage a donated prescription drug or	Drugs repackaged under (8) are misbranded and or adulterated under federal law.	Delete all of (8). The drugs repackaged under (8) do not have a lot number and/or correct expiration number. These drugs are misbranded

medical supply as necessary for storage, dispensing, administration, or transfers pursuant to both of the following: **(a) Repackaged medicine must be labeled with the drug name, strength, and expiration date and must be stored in a separate designated area until inspected and initialed by a pharmacist.** **(b) If multiple packaged donated medicines with varied expiration dates are repackaged together, the shortest expiration date must be used.** **(c) The expiration date must be no later than 1 year after the date the drug was repackaged.**		in violation of the public health code 333.17764.
Rule 338.3621		
(1) All forms required for participation in the program must be maintained ~~separate~~ **separately** from other records for 5 years**.** ~~and shall be readily retrievable for inspection at the request of the department or its agent.~~ **Two years after the record is made, the holder of the record may make an electronic duplicate of the original record that becomes the original record. The holder of the record shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**	This would require the prescription forms documenting the dispensing of the drugs under the Program would have to be kept separate from all other prescriptions.	Change to: (1) All forms required for participation in the program must be maintained separate from other records for 5 years except for prescription dispensed under the program which must be filed with the pharmacy's other prescriptions.

Shaltry, Jennifer (LARA)

From: BPL-BoardSupport
Sent: Tuesday, April 30, 2024 4:22 PM
To: Shaltry, Jennifer (LARA)
Subject: FW: Program for Utilization of Unused Prescription Drugs

You?

From: Jordan Marchetti <jordan.marchetti@tdsrx.com>
Sent: Tuesday, April 30, 2024 4:19 PM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Program for Utilization of Unused Prescription Drugs

This is a great idea in theory, but (as someone who owns multiple pharmacies)no one will be willing to participate if over regulated. It will have to be at the recipient's discretion(honor system) to determine if the donated product is still viable and even then it can't be verified. No one can spend time verifying product viability and provide this service effectively.

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Jordan Marchetti PharmD
President - TDS Inc.

Phone: (906)774-3654 (Ext. 130)
Fax: (906)774-5502

Przybylo, Kerry (LARA)

From: Martha O'Connor <marthaoconnor411@gmail.com>
Sent: Friday, May 17, 2024 8:20 AM
To: BPL-BoardSupport
Subject: Comments on Program for Utilization of Unused Prescription Drugs

Dear Bureau of Professional Licensing:

I am submitting my comments regarding the rule set entitled Pharmacy - Program for Unused Prescription Drugs and recommend the following edits.

1. R 338.3617 Inspection and storage of donated prescription drugs; destruction; recall.

Subrule (5) should contain the word unused to match subrule 4. The suggested change is as highlighted below:

(5) A participating pharmacy or charitable clinic shall create and maintain a destruction and disposal record for donated **unused** **prescription** drugs that are destroyed and disposed of as a result of being expired, adulterated, recalled, or otherwise not eligible for dispensing. A participating pharmacy or charitable clinic shall maintain a destruction record for 5 years after destruction of the donated drugs. **Two years after the destruction of the donated drugs, the participating pharmacy or charitable clinic may make an electronic duplicate of the original record that becomes the original record. A participating pharmacy or charitable clinic shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**

Subrule 8(a) should identify the manufacturer on the label so that it does not fall into the FDA definition of a misbranded or adulterated drug and complies with MCL 333.17762(1). The suggested change is highlighted in yellow below.

(8) Notwithstanding any federal or state law, or rule to the contrary, a participating pharmacy may repackage a donated prescription drug or medical supply as necessary for storage, dispensing, administration, or transfers pursuant to both of the following:

(a) Repackaged medicine must be labeled with the drug name, manufacturer, strength, and expiration date and must be stored in a separate designated area until inspected and initialed by a pharmacist.

Subrule 8(c) should contain an expiration date that is not later than 6 months after it is repackaged into compliance blister packaging or 60 days after repackaged into a customized patient medication package. The 6-month time frame is needed to be consistent with FDA guidelines for repackaging of medications into compliance blister packaging. The 60-day timeframe is needed to be consistent with the CPME rules. See R 338.585(2)(vi).

(c) The expiration date must be no later than 1 year after the date the drug was repackaged into a vial no later than 6 months after repackaged into a compliance blister packaging or no later than 60 days after repackaged in to a customized patient medication package that is prepared by a pharmacist for a specific patient and contains 2 or more prescribed solid oral dosage forms.

Sincerely,
Martha O’Connor

MHA Michigan Health & Hospital Association | Leading Healthcare

May 20, 2024

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670 Lansing, MI 48909-8170

Re: Pharmacy – Program for Utilization of Unused Prescription Drugs (MOAHR #2022-62 LR)

Attention: Departmental Specialist

The Michigan Health & Hospital Association (MHA) represents all community hospitals and health systems in Michigan. Through our leadership and support of hospitals, health systems and the full care continuum, we are committed to achieving better care for individuals, better health for populations and lower per-capita costs. As such, MHA appreciates the opportunity to comment on the proposed changes to the Pharmacy – Program for Utilization of Unused Prescription Drugs (MOAHR #2022-62 LR).

We appreciate the amount of time dedicated to getting the rules prepared to this point and that the modifications are intended to streamline the process. Our questions and comments are intended to seek clarifications so we can equip our members with the best information to comply with the rules and the Department's guidance.

R338.3603 (3)(1) contains the term "charitable clinic"; however, the definition was removed from the definition section. Further clarification of the intended definition is necessary to ensure compliance among regulated entities. A link to the location containing the definition would work to streamline the rules.

R338.3608 (3)(a) references charitable clinic pharmacies and charitable clinics. The drafting is unclear as to whether only charitable clinic pharmacies are eligible, or if all pharmacies are subject to the rule. Modifying the langue to indicate the intent will create a better process for both donating and receiving facilities.

R338.3607 (2) states "Controlled substances submitted for donation must be documented and returned immediately to an eligible facility that donated the drugs." Controlled substances are not allowed under this rule. Further clarification may be necessary to ensure compliance. As written, it essentially becomes the problem of the receiving facility if they are in possession of the disallowed drugs.

R 388.3611(2) This provision does not include participating pharmacies while provision (1) does. The exclusive nature of this provision limits options for patients and should be opened to participating pharmacies.

Brian Peters, *Chief Executive Officer*
MHA Capitol Advocacy Center | 110 W. Michigan Avenue, Suite 1200 | Lansing, MI 48933 | (517) 703-8601 | www.mha.org

R338.3617(7) requires participating pharmacies and charitable clinics to notify eligible patients of recalled drugs. The intent behind this language is understandable, however the rules should note how long pharmacies and clinics are required to keep records of what they have dispensed and keep it consistent with rules for healthcare facilities. Inconsistencies in the application of this rule across provider groups will create different standards of care for patients.

R338.3621a(a)(ii) lists "healthcare provider authorized to make the donation." Does the Department anticipate separate rules outlining which healthcare providers are authorized? Providing a link to those rules or specifying them in this provision would explain the intended purpose to providers and avoid complications in administering the rule.

R338.3621a(d) Section (a)(ii) above is inconsistent with this provision as it states healthcare providers are allowed to donate, but only pharmacists are allowed to receive the donation. Charitable clinics should also likely be included in addition to healthcare providers.

R338.3621b(b) states, "The eligible participant acknowledges that the drug is donated." If the drugs are inspected for quality standards, the source of the drug seems immaterial and is some cases may make patients hesitant to take the drug. This provision gives patients the sense the drugs are considered inferior.

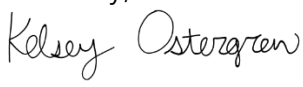
R338.3621b(c) This provision should be removed as it is not required for other prescription drugs. It creates inconsistencies administering the rules.

R338.3533(4) This provision could disincentivize participating pharmacies and charitable clinics from partaking in the program if it's left as currently written. Potential collection sites should not become a dumping ground for drugs and should be allowed to refuse donations as they see fit given their capacity.

Thanks for the opportunity to provide input on the rules. MHA's goal is to maintain consistency among rulesets and to provide clarity to providers as they navigate the prescription drug landscape. We are available to discuss any of these or other comments further and look forward to partnering with LARA to achieve success. If you have questions, please contact MHA Director, Health Policy Initiatives, Kelsey Ostergren at kostergren@mha.org.

Thank you for the opportunity to comment.

Sincerely,



Kelsey Ostergren
Director, Health Policy Initiatives
Michigan Health & Hospital Association

MediCircle

May 18th, 2024

Bureau of Professional Licensing
Department of Licensing and Regulatory Affairs
611 W. Ottawa St, PO Box 30670
Lansing, MI 48909

Re: Amendments to Mich. Admin. Code R 338.3601--3643, Program for Utilization of Unused Prescription Drugs

Attn: Jennifer Shaltry,

Via email: ShaltryJ@michigan.gov

On behalf of MediCircle, I wish to express our gratitude to the Michigan Board of Pharmacy (Board) and the Department of Licensing and Regulatory Affairs for the opportunity to comment regarding proposed amendments to rule R 338.3601--364, which modernize the Program for the Utilization of Unused Prescription Drugs. The proposed changes will further assist financially vulnerable patients by providing safe access to affordable, life-saving medications, and reduce the environmental and fiscal impact associated with the disposal of unused drugs.

MediCircle is a leading pharmaceutical redistributor that connects unused, high-value medications to financially eligible patients, for free. Our recertification model has been refined using the feedback from world-renowned physicians across the nation and adheres to the recommendations of professional organizations such as the National Association of Boards of Pharmacy (NABP), the American Cancer Society (ACS), the American Society of Clinical Oncology (ASCO), and the American Medical Association (AMA). We fully support regulations that facilitate the safe and effective redistribution of unused medication, ensuring equitable access to essential healthcare across Michigan.

While we commend the steps taken towards improving patient safety and outcomes, we propose a few amendments that would further enhance these efforts and help lower overall healthcare costs:

1) *R 338.3601. Definitions*, to include the following:

   (g) "Donor" means that any person, including an individual member of the public, or any third-party entity legally authorized to possess drugs with a license or permit in good standing in this state.

- By adding "Donor" to the definitions, the state of Michigan would allow for the donation of unused drugs by an individual or member of the public. These medications would in turn be inspected by the participating pharmacy or charitable clinic to ensure their eligibility and safety.
- The language for this amendment was crafted using Ga. Comp. R & Regs. 511-5-12
- Georgia has had one of the most successful drug redistribution programs, with over 796,000 prescriptions fulfilled from unused medications since 2017 to residents of their state (again, with no reported incidents of patient harm). The value of these prescriptions is over $64 million.[1]

2) *R 338.3607. Ineligible drugs; controlled substances prohibited.* To instead state*:*

(d) Drugs that have been outside of a health professional's control ***unless*** ~~*where*~~ *sanitation and security* ***can be inferred following inspection by a licensed pharmacist in accordance with R 338.3609*** ~~*cannot be assured*~~.

- 43 states have implemented safe and effective legislation promoting "open system" pharmaceutical redistribution which allows donations from individuals.
- Open systems of redistribution have been publicly endorsed by NABP, ACS, ASCO, and AMA.
- More than $300 million worth of medications has been safely redistributed across the United States through open systems in the past 20 years, with zero incidents of patient harm.[1]
- For any drug donation, it is essential that a pharmacist inspects the medications and uses their professional judgment to assess product integrity and safety for patient use. The Board had the foresight to include section 338.3609, which requires this inspection.
- Amendment of section 338.3607(d) would allow more patients in need throughout Michigan to safely receive donated medication.

3) 338.3621 Forms; to include a "donor donation form"

R 338.3621a Eligible ***donor donation form,*** *facility donation form, manufacturer donation form; requirements.*

Rule 21a. An eligible ***donor****, facility****,*** *or manufacturer donation form must include all of the following information:*

(a) The following information for the ***donor,*** *eligible facility****,*** *or manufacturer that is donating prescription drugs:*

(i) The name, address, telephone number, and license number, ***if applicable****.*

(ii) The name, dated signature, and license number of the pharmacist or healthcare provider authorized to make the donation, if applicable.

(b) A statement of the eligible ***donor,*** *facility****,*** *or manufacturer's intent to participate in the program and donate to the participating pharmacy or charitable clinic identified on the form.*

(c) A statement that the unused medication is eligible for donation as defined by R 338.3605 and R 338.3607.

(d) ~~*(c)*~~ *The name, address, and telephone number of the participating pharmacy or charitable clinic that is receiving the donation.*

(e) ~~*(d)*~~ *The name, license number, and dated signature of the pharmacist authorized to receive the donation.*

(f) ~~*(e)*~~*The date the donation was received by the participating pharmacy or charitable clinic.*

(g) ~~*(f)*~~ *An attestation that the transaction complies with the requirements of the Drug Supply Chain Security Act, Public Law 113-54, or is subject to a waiver, exemption, or exception by the FDA.*

- The proposed changes enhance patient safety and align with the broader, added definition of the term "donor", ensuring consistency across all Program materials.
- Additionally, these amendments align with quality assurance steps seen in other states with established, successful open systems of redistribution.

4) R 338.3627 Handling fee; to minimize patient out-of-pocket costs

Rule 27. (1) A participating pharmacy or charitable clinic may charge the eligible participant receiving a donated prescription drug 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. A participating pharmacy or charitable clinic shall use reasonable efforts to ensure the handling fee does not exceed the total cost of obtaining the same drug outside the program. ***Nothing shall prevent the participating pharmacy or charitable clinic from accepting coverage of any applicable fees from another party when eligible participants may be unable to cover the cost.***

- All patients in Michigan should have access to affordable medications.
- Prescription abandonment rates increase as out of pocket costs increase, with non-adherence seen at payments as low as $10.[2] Shipping and handling alone may exceed that, which many patients may not be able to afford.
- Granting other parties the ability to pay on behalf of an eligible patient would increase the number of Michigan residents who can benefit from this program.

By adopting these amendments, Michigan can safely enable the redistribution of unused medications, ensuring that more residents benefit from these critical resources. Approximately 1.67 million Michigan residents face challenges in affording their medications.[3–5] Medication treatment plans are often adjusted due to adverse reactions or disease progression, leading to the disposal of viable, unused, and unexpired medications—it is estimated that approximately $193 million worth of usable medication is discarded in Michigan every year.[3–6]

Thank you for considering our position on this vital issue. We are committed to collaborating with the Board to optimize the impact of this commendable program - please feel free to reach out with any additional questions or requests for additional materials.

Sincerely,

Eliza Sternlicht

Eliza Sternlicht
Co-Founder & COO
eliza@medicirclerx.com

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4. U.S. Census Bureau QuickFacts: Michigan. Accessed May 8, 2024. https://www.census.gov/quickfacts/fact/table/MI/PST045223
5. Kirzinger A, Montero A, Sparks G, Valdes I, Published LH. Public Opinion on Prescription Drugs and Their Prices. KFF. Published August 21, 2023. Accessed May 8, 2024. https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
6. Law AV, Sakharkar P, Zargarzadeh A, et al. Taking stock of medication wastage: Unused medications in US households. *Res Soc Adm Pharm RSAP*. 2015;11(4):571-578. doi:10.1016/j.sapharm.2014.10.003