Michigan Office of Administrative Hearings and Rules
MOAHR-Rules@michigan.gov

AGENCY REPORT TO THE JOINT COMMITEE ON ADMNINISTRATIVE RULES (JCAR)

1. Agency Information

Agency name:
Licensing and Regulatory Affairs

Division/Bureau/Office:
Bureau of Professional Licensing

Name of person completing this form:
Jennifer Shaltry

Phone number of person completing this form:
517-241-3085

E-mail of person completing this form:
ShaltryJ1@michigan.gov

Name of Department Regulatory Affairs Officer reviewing this form:
Elizabeth Arasim

2. Rule Set Information

MOAHR assigned rule set number:
2022-62 LR

Title of proposed rule set:
Pharmacy – Program for Utilization of Unused Prescription Drugs

3. Purpose for the proposed rules and background:

The purpose of the Pharmacy – Program for Utilization of Unused Prescription Drugs is to establish, implement, and administer a statewide unused prescription drug repository and distribution program consistent with the public health and safety, where unused or donated prescription drugs, other than controlled substances, may be transferred from an eligible facility or manufacturer to a pharmacy or a charitable clinic that elects to participate in the program, under section 17775 of the code, MCL 333.17775.

The rules were promulgated in 2014 and require a review and updates.

4. Summary of proposed rules:

The proposed rules include the following modifications: update the rules; allow drugs that include a USP-recognized method to detect improper temperature variations in the donation packaging; after two years allow an electronic duplicate of an original record; update the requirements for donated prescription drugs; delete the form required by a resident of an eligible facility; allow forms similar to the department forms to be used by participants; allow a pharmacy to repackage donated medications; and modify the requirements for a handling fee.

5. List names of newspapers in which the notice of public hearing was published and publication dates:

The Mining Journal, April 27, 2024.
Flint Journal, April 30, 2024.
Grand Rapids Press, April 30, 2024.

6. Date of publication of rules and notice of public hearing in Michigan Register:
5/15/2024

7. Date, time, and location of public hearing:
5/20/2024 09:00 AM at Room UL-4 , 611 W. Ottawa St, Lansing, Michigan

8. Provide the link the agency used to post the regulatory impact statement and cost-benefit analysis on its website:
https://ARS.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=1421

9. List of the name and title of agency representative(s) who attended the public hearing:
Jennifer Shaltry, Specialist, Bureau of Professional Licensing.

10. Persons submitting comments of support:
Eliza Sternlict, MediCircle.

11. Persons submitting comments of opposition:
Jordan Marchetti, PharmD, TDS, Inc.

12. Persons submitting other comments:
Rose Baran, PharmD, self; Martha O'Connor, self; Kelsey Ostergren, Michigan Health & Hospital Association; Eliza Sternlict, MediCircle.

13. Identify any changes made to the proposed rules based on comments received during the public comment period:

	Name & Organization	Comments made at public hearing	Written Comments	Agency Rationale for Rule Change and Description of Change(s) Made	Rule number & citation changed
1	Eliza Sternlicht, MediCircle		Commenter suggested changing the rule to permit donated drugs that have been held outside of a health professional's control to be accepted when sanitation and security can be inferred following inspection by a licensed pharmacist.	The board agreed with the commenter's suggestion, except that MCL 333.17775(5)(b)(iii) requires the sanitation and security of donated drugs to be assured rather than inferred. So the board determined to use the word "assured" instead of "inferred."	R 338.3607 (1)(d)
2	Martha O'Connor		Commenter suggested adding the word, "unused" before "prescription drugs" so the language was consistent with R 338.3617(4).	The board agreed with the commenter's suggestion to use consistent language between R 338.3617(4) and (5).	R 338.3617 (5)
3	Martha O'Connor		Commenter suggested requiring the manufacturer of the drug to be listed on the label for repackaged medicine.	The board agreed that the manufacturer name should be included on the label of repackaged medicine.	R 338.3617 (8)(a)

4	Martha O'Connor		Commenter suggested modifying the expiration date for repackaged medicine to no later than 6 months if repackaged into a vial, and no later than 60 days if repackaged into a blister pack or customized patient medication package that is prepared by a pharmacist for a specific patient and contains 2 or more prescribed solid oral dosage forms.	The board agreed to the suggestion with the addition of a reference to the Customized Patient Medication Package rule, R 338.525.	R 338.3617 (8)(c)
5	Rose Baran		Commenter suggested records of prescriptions dispensed under the program should be filed with the pharmacy's other prescriptions rather than stored separately.	The board agreed with the suggestion to that prescription records for drugs dispensed under the program should be filed with the pharmacy's other prescription records.	R 338.3621 (1)

6	Eliza Sternlicht, MediCircle		Commenter suggested modifying the requirements in the donation form to permit a donor other than an eligible facility or manufacturer to donate drugs; collecting the license number for the donor, facility, or manufacturer only if applicable; adding a required statement that the unused medication is eligible for donation as defined by R 338.3605 and R 338.3607; and renumbering the subrules.	The board agreed with the suggested changes except for the proposal to provide for a "donor" to complete the donation form. Under MCL 333.17775(3), only an eligible facility or manufacturer may transfer unused or donated drugs to a pharmacy or charitable clinic that elects to participate in the program.	R 338.3621a
7	Eliza Sternlicht, MediCircle		Commenter suggested adding a provision that nothing shall prevent a 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 of the handling fee.	The board agreed with the suggestion to add language that nothing shall prevent a party other than the eligible participant from paying the handling fee.	R 338.3627

14.Date report completed:

9/25/2024