MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
June 4, 2024

The Michigan Board of Pharmacy Rules Committee Work Group met on June 4, 2024. The meeting was held via Zoom.

CALL TO ORDER

Jennifer Shaltry, JD, Departmental Specialist, called the meeting to order at 9:00 a.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph.
Grace Sesi, PharmD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.

Members Absent: None

Staff Present: Jennifer Shaltry, JD, Departmental Specialist,
Boards and Committees Section
Kimmy Catlin, Board Support Technician,
Boards and Committees Section

Public Present: Adam Chesler
Eliza Sternlicht
Emily Mackler
George Wang
Rose Baran

RULES DISCUSSION

Shaltry explained that today's meeting will involve reviewing the public hearing comments for the Program for Utilization of Unused Prescription Drugs MOAHR 2022-62 LR rule set.

Rule 338.3601 Definitions

The commenter stated that **R 338.3603(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.

Shaltry stated that "Charitable clinic" is defined in MCL 333.17775(2)(b). The Michigan Office of Administrative Hearings and Rules (MOAHR) directive is not to repeat definitions in the rules that are found in the statute.

Discussion was held.

The committee agreed to leave the rule as written.

The commenter stated that 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 be inspected by the participating pharmacy or charitable clinic to ensure their eligibility and safety.

Shaltry stated that MCL 333.17775(5)(b)(iii) provides that drugs that have been held outside of a health professional's control where sanitation and security cannot be assured shall not be accepted for dispensing.

Discussion was held.

The committee agreed to leave the rule as written.

Rule 338.3603 Eligibility criteria; pharmacy; charitable clinics; requirements; withdrawal

The commenter stated that R 338.3608(3)(a) referenced 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 language to indicate the intent will create a better process for both donating and receiving facilities.

Shaltry inquired if it should state charitable clinic pharmacy or all pharmacies.

Sleiman stated that a charitable clinic is a pharmacy, and the language is clear as written.

Discussion was held.

The committee agreed to leave the rule as written.

Rule 338.3607 Ineligible drugs; controlled substances prohibited.

Subrule (1)(d)

The commenter suggested the following language "(d) Drugs that have been ~~held~~ 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~~."

Discussion was held.

The committee agreed to the suggested change pending Department review.

Subrule (2)

The commenter recommended deleting R 338.3607(2) as subrule (1) already states controlled substances must not be accepted under the program.

Discussion was held.

The committee agreed to leave the rule as written.

The commenter stated that 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.

Shaltry stated this would require a statutory change.

Discussion was held.

The committee agreed to leave the rule as written.

Rule 338.3609 Standards and procedures for inspecting ~~Donated~~ **donated** prescription drugs

Subrule (1)(c)

The commenter recommended changing subdivision (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."

Shaltry stated that this comment was previously received and discussed after the first public hearing. The committee requested the department to conduct research after which

the following language was incorporated into the draft that was submitted to the public hearing held on May 20, 2024: (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.

Discussion was held.

The committee agreed to leave the rule as written.

Rule 338.3611 Donated prescription drugs; eligible facility, manufacturer requirements.

The commenter stated that subrule (2) does not include participating pharmacies while subrule (1) does. The exclusive nature of this provision limits options for patients and should be opened to participating pharmacies.

Discussion was held.

The committee agreed to leave the rule as written.

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

Subrule (5)

The commenter stated that subrule (5) should contain the word “unused” to match subrule (4).

The committee agreed to the recommended change.

Subrule (7)

The commenter stated that 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.

Discussion was held.

The committee agreed to leave the rule as written.

Subrule (8)

The commenter recommended deleting all of subrule (8). The drugs repackaged under subrule (8) do not have a lot number and/or correct expiration number. These drugs are misbranded in violation of the public health code, MCL 333.17764.

Discussion was held.

The committee agreed not to delete subrule (8).

Subrule (8)(a)

The commenter stated that the label should identify the manufacturer so that it does not fall into the FDA definition of a misbranded or adulterated drug and complies with MCL 333.17762(1).

Discussion was held.

The committee agreed to add the manufacturer or NDC number.

Subrule (8)(c)

The commenter stated that 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).

Discussion was held.

The committee agreed to change subrule 8(c) to comply with the Customized Patient Medication Package rules regarding expiration dates.

Rule 338.3621 Forms; general requirements.

Subrule (1)

The commenter stated that 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.

The committee agreed to the recommendation so the subrule will read “All forms required for participation in the program must be maintained separate from other records for 5 years except for prescriptions dispensed under the program which must be filed with the pharmacy’s other prescriptions.”

Rule 338.3621a Eligible facility donation form, manufacturer donation form; requirements.

The commenter inquired if **R 338.3621a(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.

Discussion was held.

The committee agreed to leave the rule as written.

R338.3621a(d)

The commenter stated that 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.

The commenter proposed the below changes.

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 committee agreed to change the rule as follows:

R 338.3621a Eligible facility donation form, manufacturer donation form; requirements.
Rule 21a. An eligible facility or manufacturer donation form must include all of the following information:
(a) The following information for the 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 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) The name, address, and telephone number of the participating pharmacy or charitable clinic that is receiving the donation.
(e) The name, license number, and dated signature of the pharmacist authorized to receive the donation.
(f) The date the donation was received by the participating pharmacy or charitable clinic.
(g) 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.

R 338.3621b(b) Eligible participant form; requirements.

The commenter stated if the drugs are inspected for quality standards, the source of the drug seems immaterial and, in some cases, may make patients hesitant to take the drug. This provision gives patients the sense the drugs are considered inferior.

Discussion was held.

The committee agreed to leave the rule as written.

R338.3621b(c) Eligible participant form; requirements.

The commenter stated that this provision should be removed as it is not required for other prescription drugs. It created inconsistencies administering the rules.

Discussion was held.

The committee agreed to leave the rule as written.

Rule 338.3627 Handling fee.

Subrule (1)

The commenter suggested adding that “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.”

Discussion was held.

The committee agreed to the proposed change.

Rule 338.3633 Collection of prescription drugs and other medication for destruction and disposal; requirements; limitations.

Subrule (4)

The commenter stated that 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 giving their capacity.

Discussion was held.

The committee agreed to leave the rule as written.

ADJOURNMENT

Shaltry adjourned the meeting at 10:40 a.m.

Prepared by:
Kimmy Catlin, Board Support Technician June 6, 2024
Bureau of Professional Licensing

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PROGRAM FOR UTILIZATION OF UNUSED PRESCRIPTION DRUGS

Filed with the secretary of state on

These rules become effective immediately after filing with the secretary of state unless adopted under section 33, 44, or 45a(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the department of licensing and regulatory affairs **and board of pharmacy** by sections 16145~~(3)~~, 17701, and 17775 of **the public health code,** 1978 PA 368, MCL 333.16145~~(3)~~, 333.17701, and 333.17775 and Executive Reorganization Order ~~No.~~ **Nos. 1991-9, 1996-2, 2003-1, and** 2011-4, **MCL 338.3501, 445.2001, 445.2011, and** ~~MCL~~ 445.2030)

R 338.3601, R 338.3603, R 338.3605, R 338.3607, R 338.3609, R 338.3611, R 338.3615, R 338.3617, R 338.3621, R 338.3625, R 338.3627, R 338.3629, R 338.3631, R 338.3633, R 338.3635, R 338.3637, R 338.3639, R 338.3641, and R 338.3643 of the Michigan Administrative Code are amended, R 338.3621a, R 338.3621b, R 338.3621c, and R 338.3621d are added, and R 338.3613, R 338.3619, and R 338.3623 are rescinded, as follows:

R 338.3601~~.~~ Definitions.

Rule 1. **(1)** As used in ~~this part~~ **these rules**:

~~(a) "Charitable clinic" means a charitable nonprofit corporation or facility that meets all of the following requirements:~~

~~(i) Is organized as a not-for-profit corporation pursuant to the nonprofit corporation act, 1982 PA 162, MCL 450.2101 to 450.3192.~~

~~(ii) Holds a valid exemption from federal income taxation issued pursuant to section 501(a) of the internal revenue code, 26 USC 501.~~

~~(iii) Is listed as an exempt organization under section 501(c) of the internal revenue code, 26 USC 501.~~

~~(iv) Is organized under or operated as a part of a health facility or agency licensed under article 17 of the code, MCL 333.20101 to 333.20211.~~

~~(v) Provides on an outpatient basis for a period of less than 24 consecutive hours to persons not residing or confined at the facility advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health.~~

~~(vi) Has a licensed pharmacy.~~

(~~b~~**a**) "Chemotherapeutic agent" means a chemical agent used for treating various forms of cancer generally by killing the cancer cells.

(~~e~~**b**) "Code" means **the public health code,** 1978 PA 368, MCL 333.1101 to 333.25211.

~~(d) "Eligible facility" means a medical institution as that term is defined in R 338.486.~~

(**ec**) "Department" means the department of licensing and regulatory affairs~~, bureau of health care services~~.

(d) "Eligible facility" means a medical institution as that term is defined in R 338.486.

~~(f) "Eligible participant" means an individual who meets all of the following requirements:~~

~~(i) Is a resident of this state.~~

~~(ii) Is eligible to receive medicaid or medicare or has no health insurance and otherwise lacks reasonable means to purchase prescription drugs, as prescribed in these rules.~~

(e) "FDA" means the Federal Food and Drug Administration.

(**gf**) "Hazardous waste" means hazardous waste as **that term is** defined in R 299.9203.

~~(h) "Health professional" means any of the following individuals licensed and authorized to prescribe and dispense drugs or to provide medical, dental, or other health-related diagnoses, care, or treatment within the scope of his or her professional license:~~

~~(i) A physician licensed to practice medicine or osteopathic medicine and surgery under part 170 or 175 of the code, MCL 333.17001 to 333.17088 or 333.17501 to 333.17556.~~

~~(ii) A physician's assistant licensed under part 170, 175, or 180 of the code; MCL 333.17001 to 333.17088, 333.17501 to 333.17556, or 333.18001 to 333.18058.~~

~~(iii) A dentist licensed under part 166 of the code, MCL 333.16601 to 333.16648.~~

~~(iv) An optometrist licensed under part 174 of the code, MCL 333.17404 to 333.17437.~~

~~(v) A pharmacist licensed under part 177 of the code, MCL 333.17701 to 333.17780.~~

~~(vi) A podiatrist licensed under part 180 of the code, MCL 333.18001 to 333.18058.~~

(g) "Original sealed and tamper-evident packaging" means unopened, tamper-evident packaging, as that term is defined in USP, Chapter 659, "Packaging and Storage Requirements," including, but not limited to, an unopened unit-dose container or a multiple-dose container, as those terms are defined in USP, Chapter 659, "Packaging and Storage Requirements," and immediate, secondary, and tertiary packaging.

(~~i~~**h**) "Program" means the statewide unused prescription drug repository and distribution program known as the program for utilization of unused prescription drugs that is established in section 17775 of the code, MCL 333.17775.

(~~j~~**i**) "Unit dose package" means a package that contains a single dose drug with the name, strength, control number, and expiration date of that drug on the label.

(~~k~~**j**) "Unit of issue package" means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

(k) "USP" means the United States Pharmacopeia, published by the United States Pharmacopeial Convention.

(l) "USP-NF" means the United States Pharmacopeia National Formulary.

(~~l~~**m**) "Waste disposal facility" means a waste diversion center or disposal facility that ~~is in compliance~~**complies** with the natural resources and environmental protection act, 1994 PA 451, MCL 324.101 to 324.90106, for processing or disposal.

(2) Terms defined in the code have the same meaning when used in these rules unless otherwise defined in these rules.

R 338.3603. Eligibility criteria; pharmacy; charitable clinics; requirements; withdrawal.

Rule 3. (1) To be eligible for participation in the program **and to accept donated prescription drugs**, a pharmacy or charitable clinic shall comply with all applicable federal and state laws,

including laws applicable to the storage and distribution of drugs and the appropriate ~~licensure~~ **licensing** standards, and shall hold an active, nonrestricted, ~~state of Michigan~~ license **in this state** ~~in good standing~~.

(2) Participation in the program is voluntary.

(3) A pharmacy or charitable clinic may elect to participate in the program **and accept donated prescription drugs** by providing, on a form provided by the department, ~~written notification to the department of~~ all ~~of~~ the following:

(a) The name, ~~street~~ address, ~~and~~ telephone number**, and license number** of the pharmacy **and charitable clinic pharmacy licensed under article 15 of the code, MCL 333.16101 to 333.18838,** or charitable clinic **licensed under article 17 of the code, MCL 333.20101 to 333.22260.**~~, and any state of Michigan license or registration number issued to the pharmacy or charitable clinic.~~

(b) For a charitable clinic, evidence that the charitable clinic meets the requirements ~~defined~~ in ~~R 338.3601(a)~~ **section 17775(2)(c) of the code, MCL 333.17775**.

(c) The name and license number of the responsible pharmacist employed by or under contract with the pharmacy or charitable clinic.

(d) A statement signed and dated by the responsible pharmacist indicating that the pharmacy or charitable clinic meets the eligibility requirements under this rule and shall comply with the requirements of the program.

(4) A **participating** pharmacy or charitable clinic may withdraw from participation in the program ~~at any time~~ by providing written notice to the department on a form provided by the department. All of the following information ~~shall~~ **must** be included on the notice of withdrawal form:

(a) Name, address, telephone number, and ~~state of Michigan~~ license ~~or registration~~ number of **the participating** pharmacy or charitable clinic.

(b) Name and dated signature of the responsible pharmacist, attesting that the **participating** pharmacy or charitable clinic ~~will~~ **shall** no longer participate in the program.

(c) Date of withdrawal.

R 338.3605 Eligible prescription drugs.

Rule 5. (1) All non-controlled prescription drugs, except those specified in R 338.3607, that have been approved for medical use in the United States, are listed in the ~~United States pharmacopeia and the national formulary (usp-nf)~~**USP-NF**, and meet the criteria for donation established by these rules may be accepted for donation under the program.

(2) A new prescription may be transferred to another participating pharmacy or charitable clinic for dispensing.

R 338.3607~~.~~ Ineligible drugs; controlled substances prohibited.

Rule 7. (1) The following **drugs** ~~shall~~ **must** not be accepted for dispensing under the program:

(a) Controlled substances, as **described** ~~defined~~ in ~~article 7 of the code~~ **R 338.3111** ~~or by federal law~~.

(b) Expired prescription drugs.

(c) Drugs that may be dispensed only to a patient registered with the drug's manufacturer under **the FDA's** ~~federal food and drug administration~~ requirements.

(d) Drugs that have been ~~held~~ outside of a health professional's control where sanitation and security cannot be assured.

(e) Compounded drugs.

(f) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or the ~~usp-nf~~ **USP-NF** ~~shall not be donated or accepted as part of the program~~. ~~Excluded from this restriction are~~ **This subdivision does not apply to** drugs donated directly from a drug manufacturer **or an eligible facility that has ensured the integrity of the drug by enclosing in the donation packaging a USP-recognized method by which the participating pharmacy or charitable clinic can easily detect improper temperature variations.**

(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.

(b) A destruction record ~~shall~~ **must** be created and maintained for a period of 5 years after destruction ~~for~~ **of** ~~any~~ **a** controlled **substance** ~~substances destroyed~~. **Two years after the date of the destruction, the participating pharmacy or charitable clinic may make an electronic duplicate of the original record that becomes the original record of destruction. A participating pharmacy shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**

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, 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.

(2) A participating pharmacy or charitable clinic may accept donated prescription drugs from more than 1 eligible facility~~, provided that~~ **if** the **prescription drugs are donated** ~~donating is done pursuant~~ **under** ~~to~~ the terms of the program.

R 338.3611 Donated prescription drugs; eligible facility**, manufacturer** requirements.

Rule 11. (1) An eligible facility or manufacturer may donate unused or donated prescription drugs, other than controlled substances, to a participating pharmacy or charitable clinic~~,~~ if the drug meets the requirements of these rules.

(2) A manufacturer or its representative may donate prescription drugs in complimentary starter doses, other than controlled substances, to a charitable clinic under the program~~,~~ if the drug meets the requirements of these rules.

R 338.3613 ~~Resident of eligible facility; donations permitted.~~ **Rescinded.**

~~Rule 13. (1) A resident of an eligible facility or the representative or guardian of a resident of an eligible facility may donate unused prescription drugs to be dispensed under the terms of the program.~~

~~(2) A resident of an eligible facility or the resident's representative or guardian shall complete a resident donation form prior to the eligible facility taking possession of the drugs to be donated. A copy of the resident donation form shall be sent to the participating pharmacy or charitable clinic with the donated drugs.~~

~~(3) The prescription drugs donated under the method described in this rule shall have originated from the eligible facility, and prescription drugs obtained prior to the resident being admitted to the facility shall not be accepted.~~

~~(4) The prescription drugs donated under the method described in this rule are subject to all the requirements of these rules.~~

R 338.3615 Transfer and shipment of donated drugs; requirements.

Rule 15. (1) ~~Prior to the initial~~ **The eligible facility or manufacturer shall complete and transmit the eligible facility or manufacturer donation form or a substantively similar electronic or physical form in each shipment of donated prescription drugs to the participating pharmacy or charitable clinic. This form must comply with R 338.3621a.** ~~transfer of donated drugs from an eligible facility or manufacturer to a participating pharmacy or charitable clinic, the eligible facility or manufacturer shall complete the eligible facility donation form. The eligible facility or manufacturer shall transmit the completed eligible facility donation form to the participating pharmacy or charitable clinic and retain a copy for its records.~~

~~(2) A completed transfer form shall be included in each shipment of donated drugs from an eligible facility or manufacturer to a participating pharmacy or charitable clinic.~~

(~~3~~**2**) Donated drugs under the program ~~shall~~ **must** be shipped from the eligible facility or manufacturer to the participating pharmacy or charitable clinic via common or contract carrier.

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

Rule 17. (1) ~~A~~ **Before dispensing a donated drug, a** licensed pharmacist**,** employed by or under contract with the participating pharmacy or charitable clinic**,** shall inspect donated prescription drugs to determine, in the professional judgment of the pharmacist, that the drugs are not adulterated **or misbranded**, are safe and suitable for dispensing, and are eligible drugs. ~~The pharmacist who inspects the drugs shall sign the transfer form included with the shipment of donated drugs attesting to the above.~~

(2) The participating pharmacy or charitable clinic shall store donated drugs ~~pursuant to~~ **under** the manufacturer's guidelines or ~~usp-nf~~ **USP-NF** guidelines. Donated drugs ~~shall~~ **must be**

stored and maintained in a manner that distinguishes them physically or electronically from other non-donated inventory. ~~not be stored with non-donated inventory at any time.~~

(3) ~~When~~ **If** donated drugs are not inspected immediately upon receipt, a participating pharmacy or charitable clinic shall ~~quarantine~~ **store** the donated **prescription** drugs separately from all dispensing stock until the donated **prescription** drugs have been inspected and approved for dispensing under the program.

(4) A participating pharmacy or charitable clinic shall destroy donated prescription drugs that are not suitable for dispensing ~~pursuant to~~ **under the** protocols currently established by the pharmacy or charitable clinic for the destruction of prescription drugs. **This includes unused prescription drugs that met eligibility requirements for distribution upon receipt but were subsequently not dispensed to an eligible patient under the program.**

(5) A participating pharmacy or charitable clinic shall create and maintain a destruction and disposal record for donated **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.**

(6) If a participating pharmacy or charitable clinic receives a recall notification, the participating pharmacy or charitable clinic shall perform a uniform destruction of all ~~of~~ the recalled prescription drugs in the participating pharmacy or charitable clinic and complete the destruction record for all donated **prescription** drugs **that are** destroyed. The destruction ~~shall~~ **must** be done ~~pursuant to~~ **under the** protocols currently established by the pharmacy or charitable clinic for the destruction and disposal of prescription drugs.

(7) If a recalled drug has been dispensed, the participating pharmacy or charitable clinic shall immediately notify the eligible participant of the recalled drug ~~pursuant to~~ **under** established drug recall procedures.

(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, 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.

R 338.3619 ~~Record keeping; inventory; requirements.~~ **Rescinded.**

~~Rule 19. (1) A participating pharmacy or charitable clinic shall keep records in conform with these rules and all applicable federal and state laws, rules, and regulations.~~

~~(2) A participating pharmacy or charitable clinic shall maintain documented policies and procedures that will address all the requirements of these rules.~~

~~(3) A participating pharmacy or charitable clinic shall document all of the following for each drug accepted for the program:~~
~~(a) Brand name or generic name of the drug.~~
~~(b) Name of the manufacturer or national drug code number (ndc#).~~
~~(c) Quantity and strength of the drug.~~
~~(d) Lot number of medication if available.~~
~~(e) Expiration date of medication.~~
~~(f) Date the drug was donated and the date the drug was subsequently dispensed.~~
~~(g) Name of the eligible facility that donated the drug and the eligible participant subsequently dispensed the drug.~~
~~(h) The prescription from a health care professional.~~
~~(4) All records required for participation in the program shall be maintained separate from other records for 5 years and shall be readily retrievable for inspection at the request of the department or its agent.~~

R 338.3621 Forms; ~~eligible facility donation form, resident donation form, eligible participant form, transfer form, destruction form;~~ **general** requirements.

Rule 21. ~~(1) An eligible facility donation form shall include all of the following information:~~

~~(a) An eligible facility's or manufacturer's name, address, and telephone number; the name, dated signature, and license number of pharmacist or health care provider authorized to donate the drugs; and, the license number of the facility or manufacturer.~~

~~(b) A statement of the facility's intent to participate in the program and donate eligible prescription drugs to the participating pharmacy or charitable clinic identified on the form.~~

~~(c) The receiving participating pharmacy's or charitable clinic's name, address, and telephone number.~~

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

~~(e) The date the donation was received.~~

~~(2) A resident donation form shall include all of the following information:~~

~~(a) The eligible facility's name, address, state of Michigan license or registration number, and telephone number; and the name, dated signature, and license number of pharmacist or health care provider authorized to donate the drugs.~~

~~(b) The resident's name and dated signature, or the name and dated signature of the resident's representative or guardian.~~

~~(c) Attestation to the following statement, "As the legal owner of the listed prescription drug(s), I agree to voluntarily donate the listed eligible unused drugs to the program for utilization of unused prescription drugs."~~

~~(d) The drug brand name or generic name, the name of manufacturer or national drug code number (ndc#), the quantity and strength of the drug, and the drug's expiration date.~~

~~(e) The date of the donation.~~

~~(f) The name, address, telephone number and state of Michigan license or registration number of the pharmacy or charitable clinic receiving donated unused prescription drug.~~

~~(g) The date the donated drugs are received by the pharmacy or charitable clinic.~~

~~(h) The name, state of Michigan license or registration number, and dated signature of the authorized pharmacist or health care provider receiving the donated prescription drug.~~

~~(3) The eligible participant form shall include all of the following information:~~

~~(a) The participating pharmacy's or charitable clinic's name, address, telephone number, state of Michigan license or registration number, and the name, state of Michigan license or registration number, and dated signature of dispensing pharmacist.~~

~~(b) The drug's brand name or generic name, the name of manufacturer or national drug code number (ndc#), the quantity and strength of the drug, the date the drug was dispensed, and the drug's expiration date.~~

~~(c) The eligible participant's name, date of birth, address, and dated signature.~~

~~(d) Attestation of all of the following:~~

~~(i) The eligible participant is a resident of this state.~~

~~(ii) The eligible participant is eligible to receive medicare or medicaid or is uninsured and does not have prescription drug coverage.~~

~~(e) The eligible participant acknowledges that the drugs have been donated.~~

~~(f) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the poison prevention packaging act, being 15 U.S.C. §1471–1477.~~

~~(4) The transfer form shall include all of the following information:~~

~~(a) The eligible facility or manufacturer's name, state of Michigan license or registration number, address, telephone number, and the name, dated signature, and state of Michigan license number of the responsible pharmacist.~~

~~(b) The date of donation.~~

~~(c) The drug's brand name or generic name, the name of manufacturer or national drug code number (ndc#), the quantity and strength of the drug, and the drug's expiration date.~~

~~(d) The pharmacist of the eligible facility or manufacturer shall attest to the following statement, "I certify that the prescription drugs listed on this form for donation are eligible for donation and meet the requirements for prescription drugs under the program, including any storage requirements."~~

~~(e) The receiving participating pharmacy's or charitable clinic's name, address, and telephone number, and name and state of Michigan license number of responsible pharmacist authorized to receive the donation.~~

~~(f) The responsible pharmacist shall sign and date the transfer form attesting to the following statement, "Upon receipt and inspection of the above listed donated prescription drugs, it is in my professional judgment that these drugs are not adulterated, are safe and suitable for dispensing, and are eligible drugs."~~

~~(5) The destruction form shall include all of the following:~~

~~(a) The participating pharmacy's or charitable clinic's name, state of Michigan license number, address, telephone number, the name, dated signature, and license number of the responsible pharmacist.~~

~~(b) The drug's brand name or generic name, the name of the manufacturer or national drug code number (ndc#), the quantity and strength of the drug, and the drug's expiration date.~~

~~(c) The reason for destruction of the drug.~~

~~(d) The name, title, and dated signature of the witness.~~

~~(e) The date of destruction.~~

~~(f) If off-site disposal is used, the name of the firm destroying or disposing the drug, the name and dated signature of the person at the firm destroying or disposing the drug, and the date of disposal.~~

(~~6~~**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.**

(~~7~~**2**) The department shall make available all forms required by the program. The forms ~~shall~~**must** be available at no cost from the Department of Licensing and Regulatory Affairs, Bureau of **Professional Licensing** ~~Health Care Services~~, 611 ~~W.~~**West** Ottawa ~~St.~~ **Street,** Lansing, ~~MI~~ **Michigan** 48909 or on the department's website at ~~www.michigan.gov/healthlicense~~ https://www.michigan.gov/lara/bureau-list/bpl/resources/special-programs/cancer-drug-repository-program-and-utilization-of-unused-prescription-drugs-program?sc_site=lara. **A participant of the program may also use a substantively similar electronic or physical form for all forms required by the program.**

(3) A participating pharmacy or charitable clinic shall maintain documented policies and procedures that address all the requirements of these rules.

(4) A participating pharmacy or charitable clinic shall keep records as required under these rules and all applicable federal and state laws, rules, and regulations.

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

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

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

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

(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 facility or manufacturer's intent to participate in the program and donate to the participating pharmacy or charitable clinic identified on the form.

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

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

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

(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.

R 338.3621b Eligible participant form; requirements.

Rule 21b. The eligible participant form must include all of the following information before receiving the first donated prescription drug:

(a) An attestation from the eligible participant that includes both of the following:

(i) The eligible participant is a resident of this state.

(ii) The eligible participant is eligible to receive medicare or medicaid or is uninsured and does not have prescription drug coverage.

(b) The eligible participant acknowledges that the drug is donated.

(c) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the Poison Prevention Packaging Act of 1970, 15 USC 1471 to 1477.

R 338.3621c Transfer form; requirements.

Rule 21c. A participating pharmacy or charitable clinic shall document on a transfer form all of the following for each donation made to the program:

(a) The following information for each prescription drug:

(i) Brand name or generic name of the drug.

(ii) Name of the manufacturer ~~or~~ and National Drug Code (NDC) Number.

(iii) Quantity and strength of the drug.

(iv) The container size.

(v) The number of containers.

(vi) The product identifier.

(vii) Date the drug was donated.

(viii) The date of the shipment, if more than 24 hours after the date of the transaction.

(ix) Name of the eligible facility that donated the drug.

(b) The name, address, telephone number, and license number of the participating pharmacy or charitable clinic receiving the donated prescription drug.

(c) The name and license number of the responsible pharmacist authorized to receive the donated prescription drug.

(d) An attestation stating that "I certify that the prescription drugs for donation are eligible for donation and meet the requirements for prescription drugs under the program, including storage requirements" made by the pharmacist or facility manager who is responsible or the eligible facility or manufacturer.

(e) An attestation stating that this 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.

R 338.3621d Destruction form; requirements.

R 21d. The destruction form must include all of the following:

(a) The name, address, telephone number, and license number of the participating pharmacy or charitable clinic.

(b) The name, license number, and dated signature of the responsible pharmacist.

(c) The following information for each donated prescription drug that is destroyed:

(i) The brand name or generic name of the drug.

(ii) The name of manufacturer or NDC number.

(iii) The quantity and strength of the drug.

R 338.3623 ~~Eligible participants; requirements.~~ **Rescinded.**

~~Rule 23. The eligible participant shall complete the eligible participant form attesting to the following statements:~~

~~(a) The eligible participant is a resident of the state of Michigan.~~
~~(b) The eligible participant is eligible to receive medicare or medicaid or does not have insurance or prescription drug coverage. Verification or written documentation shall not be required.~~
~~(c) The eligible participant acknowledges that the drugs have been donated.~~
~~(d) The eligible participant consents to a waiver of the requirement for child resistant packaging, as required by the poison prevention packaging act, 15 U.S.C. §1471–1477.~~

R 338.3625 Dispensing donated prescription drugs; requirements.

Rule 25. (1) A participating pharmacy or charitable clinic shall dispense **a** donated prescription ~~drugs~~ **drug** in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(~~3~~**2**) The ~~department and a local~~ participating pharmacy or charitable clinic shall remove ~~any~~ patient identifying information from the package ~~prior to~~ **before** dispensing the ~~drugs~~ **drug**.

(~~4~~**3**) **A participating pharmacy or charitable clinic shall not resell a** ~~Prescription drugs~~ donated **prescription drug** ~~under this program shall not be resold~~; however, a participating pharmacy or charitable clinic may collect a handling fee ~~pursuant to~~ **under** ~~the terms of~~ R 338.3627.

R 338.3627 Handling fee.

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 maximum of 300% of the medicaid standard pharmacy dispensing fee as established by the Michigan department of community health, to cover stocking and dispensing costs., provided that the~~ **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.

(2) ~~A copy of the medicaid drug dispensing fees can be obtained from the Michigan department~~ of ~~community health, 201 Townsend Street, Lansing, Michigan 48913 or on the department's website at http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-151019--,00.html .~~

~~(3)~~ A **handling fee charged for a donated** prescription drug dispensed through the program ~~shall~~ **is** not ~~be~~ eligible for reimbursement under the medical assistance program.

~~(4)~~**(3)** The eligible participant shall not be charged a handling fee if the eligible participant is receiving a professional sample ~~which~~**that** is distributed to patients at the same charitable clinic ~~whom~~**who** are ineligible for the program without a handling fee.

R 338.3629 Donation to other participating pharmacy or charitable clinic.

Rule 29. ~~The originating~~ **A** participating pharmacy or charitable clinic may donate **prescription** drugs **that it has received** ~~donated~~ under ~~this~~ **the** program to other participating pharmacies or charitable clinics for use ~~pursuant to~~ **under** the program. The participating pharmacy or

charitable clinic donating the **prescription** drugs shall complete a transfer form **required under R 338.3621c**.

R 338.3631 Registry; creation.

Rule 31. The department shall establish and maintain a participating pharmacy and charitable clinic registry for the program on the department's website. The registry ~~shall~~ **must** include the **name, address, and telephone number of the** participating pharmacy~~'s~~ or charitable ~~clinic's~~ **clinic and** ~~name, address, and telephone number, and the contact name of~~ the **name of the** responsible pharmacist.

R 338.3633 Collection of prescription drugs and other medication for destruction and disposal; requirements; limitations.

Rule 33. (1) ~~Pursuant to~~ **Under** section 17776 of the code, MCL 333.17776, a participating pharmacy or charitable clinic shall accept from ~~any person~~**an individual** a prescription drug or ~~any other~~ **another** medication that is ineligible for distribution under the program for destruction and disposal **in accordance with 21 CFR part 1317**.

(2) Unless ~~permitted~~ **allowed** by federal law, controlled substances ~~shall~~ **must** not be collected by a participating pharmacy or charitable clinic for destruction and disposal.

(3) If a participating pharmacy or charitable clinic accepts a chemotherapeutic agent for destruction, the chemotherapeutic agent ~~shall~~ **must** not be mixed with other prescription drugs collected for disposal under the program. The chemotherapeutic agent ~~shall~~ **must** be mixed with the participating pharmacy's or charitable clinic's hazardous waste.

(4) ~~The~~ **A participating pharmacy or charitable clinic that collects prescription drugs and other medications for destruction and disposal shall collect the prescription drugs and medications** ~~collection shall occur~~ on-site at the participating pharmacy or charitable clinic and **shall follow** ~~according to~~ these rules and all applicable state and federal laws and regulations.

R 338.3635 Collection device **for ineligible drugs**; requirements.

Rule 35. A participating pharmacy or charitable clinic shall utilize a collection device to collect prescription drugs and other medications that**, upon receipt,** are ineligible for distribution under the program for destruction and disposal that meets all ~~of~~ the following ~~criteria~~ **requirements**:

(a) Is designed to allow **prescription drugs and other medications to be added to the device but allow only authorized personnel to remove the** contents **from the collection device** ~~to be added to the device but not removed, except by authorized personnel~~ for ~~the purpose of~~ destruction and disposal.

(b) **Is securely fastened to a permanent structure.**

(c) Is a tamper resistant, securely locked, substantially constructed container with a permanent outer container and a removable inner liner.

~~(b)~~**(d)** Is labeled ~~pursuant to~~ **consistent with** all applicable state and federal laws and regulations~~.~~ **and includes the following statements prominently displayed on the collection device, and also in another location near the collection device:**

(i) "Controlled substances cannot be accepted for destruction and disposal, unless allowed under federal law."

(ii) "Chemotherapeutic agents must not be placed in this collection device."

~~(c)~~**(e)** Is lined with a removable liner that is waterproof, tamper-evident, tear resistant, and capable of being sealed.

(f) The contents of the ~~liner~~ **collection device must** ~~shall~~ not be viewable from the outside **of the collection device** and the size or capacity of the ~~liner shall~~ **collection device must** be clearly marked on the outside of the ~~liner~~ **collection device**.

~~(d) Is secured in a manner that will only allow authorized personnel to remove the contents of the container for the purpose of destruction and disposal.~~

~~(e) Uses a design that is tamper resistant and is securely locked.~~

~~(f) Is securely fastened to permanent structure within the designated pharmacy area so that it cannot be removed.~~

(g) Is ~~consistently~~ monitored by security features and pharmacy personnel.

~~(h) The following statements shall be prominently placed on the collection device and shall be posted as signage near the location of the collection device, "Controlled substances cannot be accepted for destruction and disposal, unless permitted under federal law." and "Chemotherapeutic agents shall not be placed in this collection device."~~

~~(i) The collection device for the yellow jug old drugs program operated by the Great Lakes clean water organization is deemed to satisfys the requirements of this rule, provided the participating pharmacy or charitable clinic is a compliant participant in the yellow jugs old drugs program.~~

R 338.3637 Access to **collection device**; destruction of **ineligible** collected drugs.

Rule 37. (1) **For noncontrolled substances, the following rules of destruction must be followed:**

(a) ~~A~~ **An individual shall access a** collection device utilizing a removable liner ~~shall~~ only ~~be accessed~~ for the following purposes:

~~(a)~~**(i)** To remove the contents ~~to process~~ for safe, effective, and immediate transportation.

~~(b)~~**(ii)** To immediately transfer the contents to a waste disposal facility.

~~(c)~~**(iii)** To immediately transfer the contents to a responsible ~~third party~~ **individual** for transportation to a waste disposal facility.

~~(2)~~**(b)** A collection device utilizing a removable liner ~~shall~~ **must** only be accessed as follows:

~~**(a)**~~**(i)** The access ~~shall~~ **must** be done by ~~two~~ **2** personnel, ~~one~~ **1** of whom ~~shall be~~ **is** a licensed pharmacist, designated by the participating pharmacy or charitable clinic.

~~(b)~~**(ii)** Upon being accessed, the liner ~~shall~~ **must** be immediately sealed and the weight of the contents immediately recorded in the destruction and disposal log. A copy of the destruction log ~~shall~~ **must** be transferred with the sealed contents.

~~(3) A collection device for the yellow jug old drugs program operated by the Great Lakes clean water organization shall be weighed at the time the collection device leaves the pharmacy and the weight shall be recorded in the destruction and disposal log. The participating pharmacy or charitable clinic shall comply with all requirements of the yellow jug old drugs program.~~

(~~4~~ **c**) Within 1 year of collection, the contents of the collection device ~~shall~~ **must** be transferred to a waste disposal facility for destruction.

(~~5~~**d**) The contents of the collection device ~~shall~~ **must** be destroyed ~~pursuant to~~ **under** all applicable state and federal laws and regulations.

(2) For controlled substances, destruction procedures under federal law must be followed pursuant to 21 CFR 1317.95.

R 338.3639 Record keeping; policy and procedures; destruction and disposal log.

Rule 39. (1) ~~In addition to the policy and procedure requirements in R 338.3617 and R 338.3619, a~~ **A** participating pharmacy or charitable clinic shall maintain a destruction and disposal log that includes all ~~of~~ the following information:

(a) **The name** ~~Name~~, telephone number, address, and ~~state of Michigan~~ license ~~or registration~~ number of the participating pharmacy or charitable clinic.

(b) **The date** ~~Date~~, time, **and** weight of the contents of the collection device each time the contents of the collection device are removed for destruction.

(c) The name, telephone number**,** and address of ~~any third party~~ **the individual who is** responsible for transporting the contents to the waste disposal facility.

(d) The name, telephone number**,** and address of the waste disposal facility where the contents of the collection device were transferred.

(2) Copies of all contracts with transporters and waste disposal facilities ~~shall~~ **must** be stored with the destruction log, as applicable.

(3) If controlled substances are destroyed, the participant must complete the Drug Enforcement Agency Form 41 and keep it for 2 years in accordance with 21 USC 827.

R 338.3641 Transportation.

Rule 41. The contents of the collection device ~~shall~~ **must** be transferred to a waste disposal facility ~~pursuant to~~ **under** all applicable state and federal laws and regulations.

R 338.3643 Department of **health and** human services ~~and department of community health~~; inclusion in ~~rule making~~**rulemaking** process.

Rule 43. The department shall notify the director of the department of **health and** human services ~~and the director of the department of community health of an approved~~ **of a** request for ~~rule making~~**rulemaking that is approved** under **section 39 of the administrative procedures act of 1969, 1969 PA 306,** MCL 24.239**,** for ~~rule promulgation affecting~~ **any proposed rulemaking that would affect** eligible facilities or mental health or substance abuse clients. The department of **health and** human services ~~and the department of community health~~ shall provide ~~any~~ input regarding the ~~rule promulgation~~ **proposed rulemaking** to the department within 30 days ~~of~~ **after** receipt of notification of the approved request for ~~rule-making~~ **rulemaking**.