MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
JANUARY 19, 2023

The Michigan Board of Pharmacy Rules Committee Work Group met on January 19, 2023. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman, Departmental Specialist, called the meeting to order at 1:01 p.m.

ATTENDANCE

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

Members Absent: Pierre Boutros, R.Ph.

Staff Present: Andria Ditschman, JD, Departmental Specialist, Boards and Committees Section
Jacob Poynter, Manager, Licensing Division
Stephanie Wysack, Board Support Technician, Boards and Committees Section

Public Present: George Wang - SIRUM

RULES DISCUSSION

Central Fill Pharmacies – Public Comments (A copy of the public comment summary, used during today's discussion, is attached)

Ditschman stated that during the meeting, only public comments would be addressed. No new comments will be considered. The committee would need to be clear as to the reasoning if they decided to not adopt a comment.

Mollien comments:

The commenter stated that the name of the rules should be changed to Central Fill and Shared Pharmacy Services to be more inclusive to what the rules address.

The rules committee agreed to adopt the suggested change.

Ditschman stated that to be consistent with the other Board of Pharmacy rules sets, and to make them easier to locate online, the word Pharmacy should be added at the beginning of the name.

The committee agreed with the addition of the word "pharmacy".

R 338.3051 Definitions.

Subdivision (1)(b): The commenter stated that the subdivision should read "Central fill pharmacy means a pharmacy engages in dispensing function of centralized…." in order to differentiate between shared pharmacy services and central pharmacy services.

Discussion as to whether adding "dispensing" is too limiting.

Ditschman will check the rules set to see if adding "dispensing" is too limiting, and if not, the committee agreed to adopt the suggested language.

R 338.3052 Central fill pharmacies rules: prevail over other pharmacy rules.

Title: The commenter asked that the title be changed to "Central Fill and Shared Pharmacy Services" as the draft incorporated both.

Discussion held.

The committee agreed to adopt the new title.

Subrule (1): The commenter suggested this subrule be separated into two, for clarification. Language provided to update subrule (1) and for new subrule (2).

Discussion held.

The committee agreed to the updated language to subrule (1), and the language provided for new subrule (2).

R 338.3053 Centralized prescription processing; requirements.

The commenter stated that rule should read "….dispensing requirements."

Ditschman asked the committee if adding this language would mean that all duties in the rule applied to dispensing, as opposed to keeping more general, as all subdivisions may not apply to dispensing.

Sleiman stated that central fill only applied to dispensing.

Ditschman stated that central fill is specifically defined separately.

Sesi suggested adding "dispensing" and removing the language referring to MCL 333.17753.

Ditschman stated that the reference is the Code and applies.

The committee agreed to adopt the suggestion to add "dispensing" however, the language in the rule needed to be changed to apply to only dispensing. Ditschman will work on language for the board.

Pharmacy – Program for Utilization of Unused Prescription Drugs (A copy of the draft, pursuant to today's discussion, is attached)

Ditschman stated that this set of rules is required under MCL 333.17775 for the use of unused drugs. She stated that she did not make any substantive changes for the committee to review.

R 338.3605 Eligible prescription drugs.

Ditschman asked the committee to review this rule for discussion at the next committee meeting.

Poynter clarified that the department receives a few requests a year for authorization.

Ditschman stated that SIRUM submitted a draft with numerous changes and that she would be reviewing the suggested changes with the committee. Wang will provide explanations to the committee along the way.

R 338.3601 Definitions.

New subdivision (1)(m): Wang stated that this new subdivision clarified that expired drugs are not distributed.

The committee agreed with the language as presented.

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

Subdivision (3)(b): Wang stated that the original language should be used as it was clearer.

The committee agreed with the use of the original language.

R 338.3607 Ineligible drugs; controlled substances prohibited.

Subdivision (1)(f): Wang stated that proposed additional language ensures that temperature sensitive drugs can be donated if they can be stored where the temperature can be maintained.

Discussion was held.

The committee agreed with the proposed additional language.

R 338.3609 Donated prescription drugs; participating pharmacy or charitable clinic requirements.

Subdivision (1)(c): Wang stated that removing the words “lot number and” allowed for medications without lot numbers to be donated. He stated that many states do not have a lot number requirement.

Discussion held regarding whether Michigan required a lot number or not.

Sleiman explained the use of lot numbers in a retail pharmacy.

The committee agreed to the suggested change.

Subdivision (1)(d): Wang stated that shortening the subdivision to read “The drug is not expired” was clearer.

The committee agreed with the language as presented.

R 338.3613 Resident of eligible facility; donations permitted.

Subrule (2): Wang stated that the additional language provided for alternate options to be used for the donation form. The alternate option would encompass all the same information but be less cumbersome to the facility to transfer information to another form. He stated that another option would be to remove this subrule altogether.

Discussion was held.

The committee agreed to remove subrule (2).

Subrule (3): Wang stated that removal of this subrule coincides with removal of subrule (2).

Discussion was held.

The committee agreed to remove subrule (3).

R 338.3615 Transfer and shipment of donated drugs; requirements.

Subrule (1): Wang stated that the additional language provided for alternate options to be used for the donation form. The alternate option would encompass all the same information but be less cumbersome to the facility to transfer information to another form. He stated that this could also allow for one form to be used for multiple drugs in a shipment, instead of a single form for each drug in the shipment.

Discussion was held.

The committee agreed with the additional language.

Subrule (2): Wang stated that the same additional language was provided for this subrule as subrule (1), but since the language in subrule (1) was agreed to, subrule (2) could be removed.

The committee agreed to remove subrule (2).

New subrule (4): Wang stated that the language in this new proposed subrule is used in many other states.

The committee agreed to add new subrule (4).

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

Subrule (1): Wang stated that by adding the words “Prior to dispensing a donated drug,” at the beginning of the subrule, it clarified when the inspection of the drugs needed to occur.

The committee agreed with the additional language.

Wang stated that the phrase “or a substantively similar electronic or physical form” inserted into the last sentence of the subrule provided clarity, but ideally the whole sentence could be removed as it could be redundant and burdensome.

Discussion was held.

The committee agreed to remove the last sentence of subrule (1).

Subrule (2): Wang stated that additional language provided a way of identifying how storage is done and how they are differentiated between donated and non-donated drugs. This would allow for donated and non-donated drugs to be stored in the same spot.

Discussion was held.

The committee agreed with the additional language.

New subrule (8): Wang explained the new subrule provided repackaging requirements.

The committee agreed to add new subrule (8).

R 338.3619 Record keeping; inventory; requirements.

Wang stated that this rule could be consolidated with R 338.3621 to provide better clarification. He stated that if the committee did not consolidate, then subdivision (3)(d) should be removed as the lot number only needed to be included when dispensing, not when donating.

Discussion was held as to whether the lot number should be included in donation.

The committee agreed to remove subdivision (3)(d) and consolidate with R 338.3619.

Wang will provide proposed language for the consolidation for review at the next Rules Committee Work Group meeting.

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

Wang stated that language was provided throughout the rule to require the form per donation, not per drug.

The committee agreed to require a form per donation, not per drug.

Subdivision (1)(a)(ii): Wang stated that adding the phrase "if applicable" clarified who was authorized to make the donation.

The committee agreed to the additional language.

R 338.3621b Resident donation form; requirements.

Wang stated that once R 338.3619 and R 338.3621 are combined, this rule could be removed as leaving it could cause confusion.

Discussion on whether there needed to be something that was signed by the individual agreeing to donation.

Wang stated that facilities keep records of resident drugs and that qualifying drugs can already be donated without an additional form signed by the resident.

Ditschman stated that the Code references the resident or family, not the facility.

The committee agreed to remove R 338.3621b.

R 338.3621c Eligible participant form; requirements.

Subdivisions (1)(a), (b), and (c): Wang stated that these subdivisions could be removed as they were included in a standard dispensing record.

The committee agreed to remove subdivisions (1)(a), (b), and (c).

ADJOURNMENT

Ditschman stated that the Pharmacy – Central Fill Pharmacies Public Comment Summary will be voted on by the board at the meeting on February 15, 2023. She stated that another Rules Committee meeting would be needed to continue to work on Utilization of Unused Drugs and address Pharmacy – Controlled Substances.

Ditschman adjourned the meeting at 2:55 p.m.

Prepared by:
Stephanie Wysack, Board Support Technician February 8, 2023
Bureau of Professional Licensing

Central Fill Pharmacies Rules - ORR 2021-093 LR
Public Comment Summary
Rules Committee's Recommendations to December 14, 2022, Public Comments

Testimony/Comments Received:

Charlie Mollien

Title

Rule Numbers	Commenter	Comment
Title	Mollien	The rules appear to regulate both central fill pharmacies and shared pharmacy services. Consider updating the title to "Central Fill **and Shared Pharmacy Services**".
Rules Committee Response		

~~CENTRALIZED PRESCRIPTION PROCESSING~~ **CENTRAL FILL** PHARMACIES

Rule 338.3051 Definitions.

Rule Numbers	Commenter	Comment
Section (1)(b)	Mollien	Defining "central fill pharmacy" as the all encompassing term for any pharmacy engaged in centralized prescription processing incorrectly combines industry terms used to delineate between shared pharmacy services, a pharmacy engaged in non-dispensing centralized prescription processing, and central fill pharmacy, a pharmacy that engages in dispensing functions of centralized prescription processing. Modify to: **(b)**~~(a)~~ "~~Centralized prescription~~ **Central fill pharmacy**~~processing center~~" means a pharmacy ~~operated under the direction of a pharmacist~~ that ~~processes information related to the practice of pharmacy and~~ engages in **dispensing functions of** centralized prescription processing **at the request of an originating pharmacy**.

Rules Committee Response		

R 338.3051 Definitions.

Rule 1. (1) As used in **these rules** ~~parts 1 and 2 of the centralized prescription processing rules, R 338.3051 to R 338.3054~~:

(a) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.

(b)~~(a)~~ "~~Centralized prescription~~ **Central fill pharmacy**~~processing center~~" means a pharmacy ~~operated under the direction of a pharmacist~~ that ~~processes information related to the practice of pharmacy and~~ engages in centralized prescription processing **at the request of an originating pharmacy**.

~~(b) "Centralized prescription processing" is the term defined in section 17753(3) of the code.~~

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

(d) "Deliver**,**" as used in this part**,** means **the actual, constructive, or attempted transfer of** ~~to issue~~a prescription drug, including a controlled substance, directly to a patient or a patient's agent by the lawful order of a practitioner. ~~A centralized prescription~~ **Deliver does not include a central fill** ~~processing center~~ **pharmacy** that provides a prescription product to another pharmacy for subsequent issuance to a patient or a patient's agent**.** ~~has not met the definition of deliver as defined in this subrule.~~

(e) "Delivering pharmacist" means a pharmacist who is responsible for delivering a prescription directly to a patient or a patient's agent.

(f) "Delivering pharmacy" means the pharmacy that delivers the filled or refilled prescription to the patient or the patient's ~~authorized representative~~**agent**. The delivering pharmacy ~~shall~~**must** be either the originating pharmacy or the ~~centralized prescription processing center~~ **central fill pharmacy**.

(g) "Department" means the department of licensing and regulatory affairs (LARA).

~~(g)~~**(h)** "Originating pharmacy" means a pharmacy that initially receives a patient's or a prescribing practitioner's request to fill or refill a prescription.

(2) **Unless otherwise defined in these rules, a** ~~The terms~~**term** defined in the code ~~have~~**has** the same ~~meanings~~ **meaning** ~~when~~**if** used in these rules.

Rule 338.3052 ~~Centralized prescription processing~~ **Central fill pharmacies** rules; prevail over other pharmacy rules.

Rule Numbers	Commenter	Comment
Title	Mollien	The rules appear to regulate both central fill pharmacies and shared pharmacy services. Consider updating the title to "Central Fill **and Shared Pharmacy Services** rules; prevail over other pharmacy rules".
	Mollien	Divide rule into (1) and (2). Adding this clarification is necessary to reflect contemporary practice of pharmacy with shared pharmacy services and make clear the application of "dispense" as defined by MCL 333.17703(3). Delete "central fill" in first line.
Add (2)	Mollien	**(2) Shared pharmacy services for processing functions of centralized pharmacy processing that do not involve the dispensing process, such as completing claims adjudication or remote data entry, may be performed under the general supervision of a pharmacist. For this subrule, dispensing process means the physical preparing, compounding, packaging, or labeling of a drug product intended for delivery to the patient.**
Rules Committee Response		

R 338.3052 ~~Centralized prescription processing~~ **Central fill pharmacies** rules; prevail over other pharmacy rules.

Rule 2. ~~To~~**In addition to these rules, central fill pharmacies must follow all applicable board rules. However, to** the extent that ~~any rule in parts 1 and 2 of the centralized prescription processing~~ **these** rules ~~conflicts~~ **conflict** with other board ~~of pharmacy~~ rules, the provisions in ~~parts 1 and 2 of the centralized prescription processing~~ **these** rules ~~shall~~**must** prevail.

Rule 338.3053 Centralized prescription processing; requirements.

Rule Numbers	Commenter	Comment
Title	Mollien	Add "dispensing" to title. Centralized prescription processing; **dispensing** requirements.
Rules Committee Response		

R 338.3053 Centralized prescription processing; requirements.

Rule 3. (1) In addition to complying with the requirements of section 17753 of the code, **MCL 333.17753,** a pharmacy **must meet all of the following requirements before it either performs** ~~may perform~~ centralized prescription processing ~~services~~ or ~~outsource~~ **outsources** ~~these services~~ **centralized prescription processing** to another pharmacy**:**~~. Pharmacies that perform or outsource prescription processing services shall meet all of the following requirements:~~

(a) ~~Be licensed by the Michigan board of pharmacy~~**Hold a pharmacy license in this state**.

(b) Share sufficient patient and drug information to minimize the possibility of an adverse drug event.

(c) Maintain ~~prescription information or an equivalent record, as prescribed in section 17752(1) of the code, and the~~ records required in R 338.3054 ~~of this part~~, for 5 years **from the date of dispensing**. ~~A centralized prescription processing center and an original pharmacy~~ **The pharmacy** shall ensure that the ~~information~~**records** ~~is~~**are** readily retrievable within 48 hours after the ~~board's agent~~ **department** makes a request for the ~~information~~**records**. If the records are maintained in a digital format, a printed copy ~~shall~~**must** be made available **to the department or other authorized individual**~~immediately to the board's agent~~ upon request.

(2) The originating pharmacy shall maintain the original prescription for a period of 5 years after the date the prescription was filled.

(3) Two years after the prescription was filled, the originating pharmacy may make an electronic duplicate of the original paper prescription, which becomes the original prescription. The originating pharmacy shall present a printed copy of the electronic duplicate of the prescription to the department or board upon request.

~~(2)~~**(4)** A pharmacy engaging in centralized prescription processing ~~shall be~~**is** responsible for each function of the prescription's processing performed by that pharmacy.

~~(3)~~**(5)** A delivering pharmacist ~~shall be~~**is** responsible for complying with ~~R 338.490(4)~~ **R 338.589(4)** regarding patient counseling.

~~(4)~~**(6)** The prescription label for a prescription that was filled by a ~~centralized prescription processing center~~ **central fill pharmacy** ~~shall~~**must** identify each pharmacy that was involved in ~~preparing~~**dispensing** and delivering ~~a~~**the** prescription. A ~~centralized prescription processing center~~ **central fill pharmacy** may be identified on a prescription label by use of a unique identifier that is recognized by the delivering pharmacist. **A central fill pharmacy shall create and maintain a unique identifier and communicate the unique identifier to all pharmacies that use its services.** As used in this subrule, "unique identifier" means a unique combination of letters, numbers, or symbols that allows the delivering pharmacy to identify the specific ~~centralized prescription processing center~~ **central fill pharmacy** involved in the processing of the prescription. ~~A centralized prescription processing center shall create and maintain a unique identifier and shall communicate the unique identifier to all pharmacies that use its services.~~

~~(5)~~**(7)** A prescription that was not delivered to a patient may be transferred back to the pharmacy that filled the prescription, ~~provided that~~**if** the transfer records are maintained. A ~~centralized prescription processing center~~ **central fill pharmacy** and an originating

pharmacy shall establish procedures for the disposition of prescription medication that was not delivered to patients. This medication may be returned to stock and may be ~~re-delivered~~ **re-dispensed** without constituting a violation of R ~~338.472(1)~~ **338.503(1)**.

~~(6)~~**(8)** A pharmacy that performs or contracts for centralized prescription **processing** ~~services~~ shall comply with the procedures described in its policies and procedures manual, ~~as provided in~~**pursuant to** section 17753(2) of the code**, MCL 333.17753**.

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~~**take effect** immediately ~~after~~**upon** 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 by sections 16145(3), 17701, and 17775 of 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~~**c**) "Eligible facility" means a medical institution as that term is defined in R 338.486.

(**ed**) “Department” means the department of licensing and regulatory affairs~~, bureau of health care services~~.

~~(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.~~

(~~g~~**e**) “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.~~

~~(i) "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~~**f**) “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~~**g**) “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.

(h) “USP” means the United States pharmacopeia.

(i) “USP-NF” means the United States pharmacopeia and the national formulary.

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

(k) “Original sealed and tamper-evident packaging” shall have the same meaning as “Unopened tamper-evident packaging” as defined in USP, General Chapter 659, Packaging and Storage Requirements including but not limited to unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning as used 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 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 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 **licensed under article 15** or charitable clinic **licensed under article 17**~~, 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 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 **the** 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 **that term is** defined in article 7 of the code 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 Federal Food and Drug Administration'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 drugs donated directly from a drug manufacturer **or an eligible facility 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, which 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 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. 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, and there is no reason to believe that the drug is adulterated.

(f) The packaging does not have ~~any~~ physical signs of tampering, deterioration, compromised integrity, 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.** ~~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~~**Prior to 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, 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.

(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, which 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 rule to the contrary, a participating pharmacy may repackage a donated prescription drug or medical supply as necessary for storage, dispensing, administration, or transfers in accordance with the following:

(a) Repackaged medicine 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.

(b) If multiple packaged donated medicines with varied expiration dates are repackaged together, the shortest expiration date shall be used.

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,~~ **manufacturer donation form,** ~~resident donation form, eligible participant form, transfer form, destruction form;~~ **general** requirements.

Rule 21. (~~6~~**1**) All forms required for participation in the program must 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.~~ **Two years after the record is made, the holder of the record may make an electronic duplicate of the original record, which 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 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.

~~(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.~~

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

Rule 21a. (1) 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 will donate 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 will receive 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.

R 338.3621b Eligible participant form; requirements.

Rule 21b. (1) The eligible participant form must include all of the following information prior to receiving the first donated prescription drug:

(a) An attestation from the eligible participant that includes all 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, 15 USC 1471 to 1477.

R 338.3621c Transfer form; requirements.

Rule 21c. (1) A participating pharmacy or charitable clinic shall document all of the following for all donations made to the program on a transfer form:

(a) The following information for each prescription drug:

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

(ii) Name of the manufacturer or national drug code number (ndc#).

(iii) Quantity and strength of the drug.

(iv) Date the drug was donated.

(v) 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) The pharmacist or facility manager responsible for the eligible facility or manufacturer shall attest to the following statement, "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."

R 338.3621d Destruction form; requirements.

R 21d. (1) 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 national drug code number (ndc#).

(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 drug~~s~~.

(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 **health and human services** ~~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) The eligible participant shall not be charged a handling fee if the eligible participant is receiving a professional sample which is distributed to patients at the same charitable clinic whom 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 they have 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 **and** ~~'s 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~~**a** person a prescription drug or ~~any other~~**another** medication that is ineligible for distribution under the program for destruction and disposal.

(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; requirements.

Rule 35. A participating pharmacy or charitable clinic shall utilize a collection device to collect prescription drugs and other medications that 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 labeled ~~pursuant to~~**consistent with** all applicable state and federal laws and regulations~~.~~ **and contains the following statement prominently on the collection device, "Controlled substances cannot be accepted for destruction and disposal, unless allowed under federal law." and "Chemotherapeutic agents must not be placed in this collection device."**

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

(d) 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~~ **Is** tamper resistant and is securely locked.

(f) Is securely fastened to **a** 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~~ **must** be posted as signage near the location of the collection device, "Controlled substances cannot be accepted for destruction and disposal, unless ~~permitted~~**allowed** under federal law." and "Chemotherapeutic agents ~~shall~~**must** 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; destruction of collected drugs.

Rule 37. (1) ~~A~~ **An individual shall access a** collection device utilizing a removable liner ~~shall~~ only ~~be accessed~~ for the following purposes:

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

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

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

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

(a) 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) 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**3**) Within 1 year of collection, the contents of the collection device ~~shall~~**must** be transferred to a waste disposal facility for destruction.

(~~5~~**4**) The contents of the collection device ~~shall~~**must**be destroyed ~~pursuant to~~**under** all applicable state and federal laws and regulations.

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~~**a person** ~~third party~~ 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.

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 process.

Rule 43. The department shall notify the director of the department of **heath and** human services ~~and the director of the department of community health~~ of an approved request for rule-making under MCL 24.239 for rule promulgation affecting 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 to the department within 30 days ~~of~~**after** receipt of notification of the approved request for rule-making.