MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
SEPTEMBER 11, 2023

The Michigan Board of Pharmacy Rules Committee Work Group met on September 11, 2023. The meeting was held via Zoom.

CALL TO ORDER

Stephanie Wysack, Board Support Technician, called the meeting to order at 9:01 a.m.

ATTENDANCE

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

Members Absent: None

Staff Present: Kerry Przybylo, JD, Manager, Boards and Committees Section
Jennifer Shaltry, JD, Departmental Specialist,
Boards and Committees Section
Stephanie Wysack, Board Support Technician,
Boards and Committees Section

Public Present: George Wang - SIRUM

RULES DISCUSSION

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

Przybylo stated that the purpose of today's meeting was to review the research conducted, related to the public comments received for the public hearing held on July 13, 2023.

R 338.3609 Donated prescription drugs: participating pharmacy or charitable clinic.

Section (1)(c): Przybylo stated that the Drug Supply Chain Security Act requires that the lot number be included with all other information when transferring a prescription to a pharmacy.

Discussion was held.

The committee agreed with Baran's comment to include the lot number language provided.

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

Section (1) and (8): Przybylo asked the committee if "misbranded" should be added.

The committee agreed to the addition of "misbranded."

Section (8): The department proposed new section (8)(c) to be compliant with federal law, instead of deleting the entire section.

The committee rejected the comment to delete the section and agreed to the proposed language under new section (8)(c).

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

Przybylo stated that to be compliant with the DSCSA, the rule needed to provide transaction history in a single document. She asked the committee if the language under new section (f) was sufficient.

The committee agreed with the comment and with the suggested attestation language under new section (f).

R 338.3621c Transfer form; requirements.

Section (b): Przybylo stated that research of the DSCSA indicated that language should be added to clarify the items in the rule.

Discussion was held.

The committee agreed with the comment but asked for further research on "serial number."

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

Sections (1), (2), (3), and (4): Przybylo stated that research showed that a statement about the disposal of prescription drugs must comply with federal law requirements should be added.

Discussion was held.

The committee agreed with the comment and the language provided, referencing 21 CFR part 1317 subpart B.

R 338.3635 Collection device; requirements.

Przybylo stated that research showed that the highest federally required standards must be followed when dealing with a collection device that will receive controlled substances. Therefore, the rule could not be deleted as requested by the commenter. She proposed new language included in subrules (b), (c), and (d).

Discussion was held.

The committee rejected the comment to delete the section and agreed to use the new language proposed by the department.

Przybylo stated that these additional proposed changes, which were made to comply with DSCSA, required an additional hearing to be held.

Sesi indicated she did not want the set to go to hearing again and would like further review done by the department and the committee before this decision is made.

The committee agreed with Sesi's statement.

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

Przybylo stated that research indicated that the rule was required under the statute and could not be deleted as requested. She suggested adding subrule (3) to incorporate federal record keeping requirements.

Discussion was held.

Wang stated that if DSCSA requirements were being added back into the rules, exemption and waiver requirement language needed to be added as well. He stated that language needed to be considered carefully as to not create a burden with the level of security.

Przybylo suggested that an additional rule be added to encompass exemptions and waivers when federal law required them. This would remove the need to include the language in each individual rule.

Taylor agreed with Przybylo's suggestion of a new rule, instead of listing individually.

Wang stated that the FDA also had exemptions that should be considered.

R 338.3635 Collection device; requirements.

Sleiman stated that this rule should take into account that drug take-back containers in a retail pharmacy are different then a collection device.

Discussion held on whether the security on both should be the same.

Wang stated that some states combine them, but a charitable donation through a shipment or at the counter is not the same as a one-way transaction of a take-back container.

Boutros stated that the rules should be clearly written to differentiate between charitable donation and those for destruction. Sleiman agreed.

Przybylo indicated that this rule applied to ineligible drugs.

The committee stated that the rules needed to be reviewed again before going back to public hearing. They requested feedback from Wang on possible language for DSCSA compliance.

Wang stated that transaction history is set to be removed at the end of 2023.

ADJOURNMENT

She stated that another Rules Committee Work Group meeting would be scheduled to continue work on this set of rules as well as public comments received on the Pharmacy – Controlled Substances rules.

Przybylo adjourned the meeting at 10:12 a.m.

Prepared by:
Stephanie Wysack, Board Support Technician October 5, 2023
Bureau of Professional Licensing

Pharmacy – Program of Utilization of Unused Prescription Drugs - ORR 2022-62 LR
Public Comment Summary
Rules Committee's Recommendations and Board Decisions regarding July 13, 2023, Public Comments

Testimony/Comments Received:

Rose Baran, Pharm. D.
Sara DiBernardo, Esq. Policy Associate for SIRUM

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

Section Numbers	Commenter	Comment
(1), (3), and (4)	Baran	By definition, in MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(3)(a)	Baran	Charitable clinic is organized under or operated as part of health facility or agency listed under Article 17 MCL 333.20101 to 333.20211 but is not licensed separately under Article 17 of the code, MCL 333.20101 to 333.22260. The charitable clinic does not take possession of the drugs. It is the pharmacy of the charitable clinic that has possession of the drugs. **Suggested Change:** (a) The name, address, telephone number**, and license number** of the pharmacy **licensed under article 15 of the code, MCL 333.16101 to 333.18838,** or charitable clinic pharmacy licensed **under article 15 of the code, MCL 333.16101 to 333.18838.**
(4)	Baran	No need to develop a form if the rule is listing what the department must be told in writing when a participating pharmacy is withdrawing from participation in the program. **Suggested change:** (4) A **participating** pharmacy or charitable clinic may withdraw from

		participation in the program by providing written notice to the department. All of the following information **must** be included on the notice of withdrawal form: (a) Name, address, telephone number, and license number of **the participating** pharmacy or charitable clinic pharmacy.
Rules Committee Response	(1), (3), and (4): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. (3)(a): The committee agreed that clarification was needed. The committee suggested changing the language as follows: (a) The name, address, 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 338.20101 to 333.22260. (4): The committee elected not to make this change as the department uses a form to ensure that all submissions contain the required information.	

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.

Board Response	

Rule 338.3605 Eligible prescription drugs.

Section Numbers	Commenter	Comment
2	Baran	By definition, in MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
Rules Committee Response	The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.	

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.

Board Response	

Rule 338.3607 Ineligible drugs; controlled substances prohibited.

Section Numbers	Commenter	Comment
(1)(f)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(2)	Baran	Disposal of controlled substances is regulated by the Federal Secure and Responsible Drug Act of 2010 and the rules promulgated under that Act, see 21 CFR Part 1317. The federal law is the stricter law. Eligible facility is a medical institution defined in the Pharmacy – General Rules R 338.486(a) *"Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, freestanding surgical outpatient facility, hospice, or other health facility that is licensed or approved by the state, which directly or indirectly provides or includes pharmacy services."* If an eligible facility possesses controlled substances, it is because they have a pharmacy registered with the DEA. A pharmacy must dispose of controlled substances pursuant to 21 CFR part 1317. A pharmacy donating controlled substances to another pharmacy must comply with the Pharmacy – Controlled Substances Rules, R 338.3153, and follow the DEA regulations for transfer and disposal of controlled substances. **Suggested Change:** Change subrule (2) to read: Controlled substances shall not be donated by any eligible facility. Controlled substances must be disposed of pursuant to 21 CFR Part 1317.
Entire rule	SIRUM	Agree that temperature-sensitive drugs need to be handled carefully to ensure safety. Letter of support for the rules that allow for the donation of temperature-sensitive drugs so long as the proper temperature control can be verifiably maintained during drug transit.
Rules Committee Response	(1)(f): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. (2) The committee elected not to make suggested change because controlled substances can be donated to an eligible facility and pharmacists know that they must follow federal law as part of their protocols for disposal.	

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 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~~ **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.**

Board Response	

Rule 338.3609 Donated prescription drugs; participating pharmacy or charitable clinic.

Section Numbers	Commenter	Comment
Title, and Sections (1) and (2)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic.

		Suggested Change: Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(1)(c)	Baran	21 CFR 201.18 requires a lot number on prescription drugs. *"The lot number on the label of a drug should be capable of yielding the complete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded."* In February 2023 the department gave a presentation to the board indicating one of the common pharmacy violations found was under the Pharmacy – General Rules R 338.589(1) for unlabeled or incorrectly labeled medications, i.e. lacking a lot number. Lacking a lot number would make the drug misbranded. *"A drug or device shall be deemed to be misbranded . . .if its labeling is false or misleading in any particular."* See 21 USC 352 of the Federal Food, Drug and Cosmetic Act (page 143 of link). Effective November 27, 2023, pharmacies must comply with the Drug Supply Chain Security Act, Public Law 113-54. *(Drug Supply Chain Security Act is Title II)*. The law requires the lot number of the drug along with other information be transferred to the pharmacy receiving the drug. No lot number would cause the product to be misbranded. Pharmacies may not dispense misbranded drugs, MCL 333.17764. **Suggested Change:** Change (c) to read: The drug package contains the information required by the Food Drug and Cosmetic Act and the transaction information required by the Drug Quality Security Act when a drug is transferred to the participating pharmacy or the charitable clinic pharmacy.
(1)(e) and (f)	Baran	21 CFR 201.18 requires a lot number on prescription drugs. **Suggested Change:** Add misbranded and misbranding to (e) and misbranding to (f). Change to read: (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.

Entire Rule	SIRUM	Allowing the repackaging of unit-dose packaging from LTC facilities provides patients with a more uniform and standard packaging, saves space for participating pharmacies, and will ease workflow burdens for participating pharmacy staff. SIRUM supports permitting pharmacies to repackage donations as necessary for the storage, dispensing, administration, or transfer.
Rules Committee Response	Title and (1), (2): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. (1)(c): The committee requested that the department conduct research on this suggestion and report its findings. The decision on whether to edit the rule will be made pending research results. (1)(e) and (f): The committee requested that the department conduct research on this suggestion and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	The Drug Quality and Security Act, which amends the Food, Drug and Cosmetic Act, 21 USC 301 *et.seq*, requires *outsourcing facilities* to include the lot number on the label. 21 CFR 201.18 states that *"[t]he lot number on the label of a drug should be capable of yielding the complete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded."* However, pharmacies that are not outsourcing facilities need not include the lot number under the law. 21 CFR 201.1 states the general labeling requirements for a drug in finished package form must have a label that conspicuously bears the name and place of business of the manufacture, packer, or distributor or the drug is deemed misbranded. The law requires those in the chain inspect the product to ensure it is not suspect. Therefore, having the lot number on the label would assist with that determination. The eligible participants in this program are pharmacies and charitable clinics. Outsourcing facilities are pharmacies. It is suggested that the edit include the lot number if the donation is coming from an outsourcing facility. (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. (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.
Rules Committee Response	The committee agreed with the suggested changes recommended by the department after conducting further research.

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.

Board Response	

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

Section Numbers	Commenter	Comment
(1) and (2)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(1) and (2)	Baran	Add pharmacy to eligible facility as, it is the pharmacy that possesses the drug. **Suggested Change:** (1) An eligible facility, pharmacy, or manufacturer may donate unused or donated prescription drugs, other than controlled substances, to a participating pharmacy or charitable clinic pharmacy, 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 pharmacy under the program~~,~~ if the drug meets the requirements of these rules.
Rules Committee Response	(1) and (2): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. Additionally, an eligible facility includes a medical institution that provided pharmacy services, so the suggested change was not made.	

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.

Board Response	

Rule 338.3615 Transfer and shipment of donated drugs; requirements.

Section Numbers	Commenter	Comment
(1)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(1)	Baran	Add pharmacy to eligible facility, as an eligible facility without a pharmacy may not possess drugs. Suggested change: (1) **The eligible facility, pharmacy, or manufacturer shall complete and transmit the eligible facility, pharmacy, 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 pharmacy.** (**2**) Donated drugs under the program **must** be shipped from the eligible facility pharmacy or manufacturer to the participating pharmacy or charitable clinic pharmacy via common or contract carrier.
Rules Committee Response	(1) The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. Additionally, an eligible facility includes a medical institution that provides pharmacy services, so the suggested change was not made.	

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.

Board Response	

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

Section Numbers	Commenter	Comment
(1) through (7)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(1)	Baran	Add misbranded. **Suggested Change:** (1) **Before dispensing a donated drug, a** licensed pharmacist**,** employed by or under contract with the participating pharmacy or charitable clinic pharmacy**,** shall inspect donated prescription drugs to determine, in the professional judgment of the pharmacist, that the drugs are not adulterated and or misbranded, are safe and suitable for dispensing, and are eligible drugs.
(8)	Baran	Drugs repackaged under (8) are misbranded and or adulterated under federal law. **Suggested Change**: Delete all of (8).
Rules Committee Response	(1) through (7): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. (1): The committee requested that the department conduct research on this suggestion and report its findings. The decision on whether to edit the rule will be made pending research results.	

	(8): The committee requested that the department conduct research on this suggestion and report its findings. The decision on whether to edit the rule will be made pending research results.
Research Results	(1) As stated above, if the label is missing information required under the Drug Quality Security Act, it is considered misbranded. Further, the act requires those in the chain inspect the product to ensure it is not suspect. Therefore, it is recommended that the word misbranded be added to subrule (1). (8) In addition to the requirements cited above for subrule 1, licensed pharmacies regularly repackage medication for dispensing. Drugs may need to be repackaged into a new container or have previous patient identifiers removed. Further, the proposed rule language specifically states that it is **subject to any other rule** that states the contrary. It is recommended that the language in subrule (8) be edited as referenced below. (1) **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. (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 from the date the drug was repackaged.**
Rules Committee Response	

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, 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 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 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.

Board Response	

Rule 338.3621 Forms; general requirements.

Section Numbers	Commenter	Comment
(1)	Baran	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. **Suggested Change:** Change to: (1) All forms required for participation in the program must be maintained separate from other records for 5 years except for prescription dispensed under the program which must be filed with the pharmacy's other prescriptions.
(3) and (4)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
Rules Committee Response	(1): The committee elected not to make the suggested change because keeping these files separate does not impact patient safety. (2) and (4): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.	

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 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.

Board Response	

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

Section Numbers	Commenter	Comment
(b), (c), and (e)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
	Baran	This rule must comply with federal law as stated in Drug Quality Security Act and in R 338.3621(4) and Pharmacy – General Rule R 338.583a. **Suggested Change:** Add language from Drug Quality Security Act regarding serialized transaction information.
Rules Committee Response	(b), (c and (e): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. The committee requested that the department conduct research on adding language from the DQSA and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	The Drug Supply Chain Security Act provides that those in the drug chain provide the transaction history, transaction information, and a transaction statement in a single document at the time of the transaction. If this information is not provided, a manufacture/wholesaler/pharmacy are prevented from transferring the drugs and the wholesale distributors and the dispensers are prohibited from receiving the drugs. *See Section 582(b), (c) and (d).* Further, the transaction	

	information is to be kept for 6 years from the date of the transaction. It is recommended that the following changes be made to conform with the DSCSA and R 338.3621c. **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 history, transaction information, and a transaction statement were provided in a single document at the time of the transaction in accordance with the Drug Quality Security Act and the Drug Supply Chain Security Act.**
Rules Committee Response	The committee stated that the transaction history was not needed. The remainder of the changes were approved.

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:
(ii)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 history, transaction information, and a transaction statement were provided in a single document at the time of the transaction in accordance with the Drug Quality Security Act and the Drug Supply Chain Security Act.

Board Response	

Rule 338.3621c Transfer form; requirements.

Section Numbers	Commenter	Comment
Title and section (b)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
	Baran	This rule must comply with federal law as stated in Drug Quality Security Act and R 338.3621(4) and Pharmacy-General Rule R 338.583a. **Suggested Change:** Add language from Drug Quality Security Act regarding serialized transaction information.
Rules Committee Response	Title and section (b): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. The committee requested that the department conduct research on adding language form the DQSA and report its findings. The decision on whether to edit the rule will be made pending research results.	

Research Results	The Drug Supply Chain Security Act provides that those in the drug chain provide transaction history, transaction information, and a transaction statement in a single document at the time of the transaction. If this information is not provided, a manufacture/wholesaler/pharmacy is prevented from transferring the drugs and the wholesale distributors and the dispensers are prohibited from receiving the drugs. See Section 582(b), (c) and (d). Further, the transaction information is to be kept for 6 years from the date of the transaction. Section 581(25) states that **transaction history** is a statement, in paper or electronic form, that includes the transaction information for each prior transaction going back to the manufacturer of the product. The Drug Quality Security Act section 581(26) outlines **transaction information** as: (A) The proprietary or established name(s) of the product. (B) The strength and dosage form of the product. (C) The National Drug Code Number of the product. (D) The container size. (E) The number of containers. (F) The lot number of the product. (G) The date of the transaction. (H) The date of the shipment, if more than 24 hours after the date of the transaction. (I) The business name and address of the person from whom ownership is being transferred. (J) The business name and address of the person to whom ownership is being transferred. Section 581(27) states that the **transaction statement** is a statement, in paper or electronic form, that the entity transferring ownership in a transaction has complied with the following: (A) Is authorized as required under the DSCSA. (B) Received the product from a person that is authorized as required under the DSCSA. (C) Received transaction information and a transaction statement from the prior owner of the product, as required under section 582. (D) Did not knowingly ship a suspect or illegitimate product. (E) Had systems and processes in place to comply with verification requirements under section 582. (F) Did not knowingly provide false transaction information.

	(G) Did not knowingly alter the transaction history. It is suggested that to comply with the Drug Quality Security Act, the following language be added to the form. **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 all donations 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 lot number and expiration date of the product.** ~~(iv)~~**(vii)** Date the drug was donated. **(viii) The date of the shipment, if more than 24 hours after the date of the transaction.** ~~(v)~~**(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 "In accordance with the Drug Quality Security Act and the Drug Supply Chain Security Act, I have received the transaction history, a transaction statement, and transaction information from the eligible donating facility."**
Rules Committee Response	The committee stated that the transaction history will no longer be required, and that information should be deleted. The remainder of the changes were approved.

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 all donations 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 National Drug Code (NDC) Number.

(iii) Quantity and strength of the drug.

(iv) The container size.

(v) The number of containers.

(vi) The lot number and expiration date of the product.

~~(iv)~~**(vii)** Date the drug was donated.

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

~~(v)~~**(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 "In accordance with the Drug Quality Security Act and the Drug Supply Chain Security Act, I have received the transaction history, a transaction statement, and transaction information from the eligible donating facility."

Board Response	

Rule 338.3621d Destruction form: requirements.

Section Numbers	Commenter	Comment
(a)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."

Rules Committee Response	(a): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.

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 and NDC number.

(iii) The quantity and strength of the drug.

Board Response	

Rule 338.3625 Dispensing donated prescription drugs; requirements.

Section Numbers	Commenter	Comment
(1), (2), and (3)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
Rules Committee Response	(1), (2), and (3): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.	

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.

Board Response	

Rule 338.3627 Handling fee.

Section Numbers	Commenter	Comment
(1) and (3)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
(2)	Baran	Subrule (2) is no longer needed because in subrule (1) the use of the Medicaid standard dispensing fee was deleted. **Suggested Change:** Delete (2).
Entire rule	SIRUM	Support the proposed rule change to allow for a handling fee not to exceed the reasonable costs of participating in the program.
Rules Committee Response	(1) and (3): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. (2): The committee agreed with the commenter and recommended deleting section (2).	

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.

Board Response	

Rule 338.3629 Donation to other participating pharmacy or charitable clinic.

Section Numbers	Commenter	Comment
Title and rule content.	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
Rules Committee Response	The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.	

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**.

Board Response	

Rule 338.3631 Registry; creation

Section Numbers	Commenter	Comment
Rule content	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
Rules Committee Response	The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.	

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.

Board Response	

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

Section Numbers	Commenter	Comment
(1), (2), (3), and (4)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."

	Baran	The collection device under R 338.3633 – R 338.3641 would be confused with the collection device allowed under 21 CFR Part 1317 subpart B Disposal of Controlled Substances Collected From Ultimate Users and Other Non-Registrants. Pharmacies that have a collection device under the program would be in violation of 21 CFR part 1317 because if one controlled substance is put in the collection device it needs to comply with the federal requirements. Ultimate users are very familiar with collection devices allowed under federal law. Require all pharmacies that participate in the program to comply with 21 CFR part 1317 subpart B Disposal of Controlled Substances Collected from Ultimate Users and Other Non-Registrants. The list of 18 participating pharmacies in the program on the state website contains only one that does not participate in the DEA controlled substance public disposal. The list was last updated on August 15, 2016. **Suggested Change:** (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 by participating in the DEA controlled substance public disposal according to 21 CFR part 1317 subpart B.
Rules Committee Response	(1), (2), (3) and (4): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. The committee requested that the department conduct research to see if the language conflicted with the 21 CFR 1317 subpart B and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	MCL 333.17775 and 333.17776 allow a person to deliver to a pharmacy, health professional, or charitable clinic that participates in the program, a prescription drug or any other medication that **is ineligible for dispensing** under the program for destruction and disposal. Even though the program cannot dispense a controlled substance, it has to be ready to receive a controlled substance from a member of the public. Therefore, a collection device must be suitable to	

	receive a controlled substance. 21 CFR Part 1317 authorizes a registrant *who is authorized to be a collector* under 21 CFR 1317.40 to receive a controlled substance. These registrants must specifically modify their registration to obtain authorization to collect controlled substances. So, unless they are authorized to be a collector, they cannot receive a controlled substance to be destroyed. Therefore, it is recommended that language be inserted to close the gap to ensure that all participants have the proper registration to receive controlled substances. The recommended changes are as follows: R 338.3633 Collection of **ineligible** prescription drugs and other medication for destruction and disposal; requirements; limitations. (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 1317.**
Rules Committee Response	

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.

(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.

Board Response	

Rule 338.3635 Collection device; requirements.

Section Numbers	Commenter	Comment
Rule content	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
	Baran	Suggests deleting this rule. (For reasons stated in comment about R 338.3633).
Rules Committee Response	The committee elected not to make the suggested change of changing charitable clinic to charitable clinic pharmacy to avoid confusion as the pharmacy must be part of the clinic. The committee requested that the department conduct research on to see if the language conflicted with 21 CFR 1317 and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	This rule cannot be deleted as the statute requires participants to accept drugs that cannot be dispensed under the program. Collection receptacle requirements (for controlled substances) are found in 21 CFR 1317.75. The receptacle must be securely fastened to a permanent structure; be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner; the outer container shall prominently display a sign indicating that only Schedule II-V controlled and noncontrolled substances, are acceptable substances (Schedule I controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted.)	

	R 338.3535 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 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. ~~(d)~~**(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 **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.~~

Rules Committee Response	

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 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) 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 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.~~

Board Response	

Rule 338.3637 Access; destruction of collected drugs.

Section Numbers	Commenter	Comment
(2)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic. **Suggested Change:** Change the phrase "charitable clinic" to "charitable clinic pharmacy."
	Baran	Suggests deleting this rule. (For reasons stated in comment about R 338.3633).
Rules Committee Response	(2) The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. The committee requested that the department conduct research on to see if the language conflicted with the 21 CFR 1317 subpart B and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	This rule cannot be deleted as the statute requires participants to accept drugs that cannot be dispensed under the program. Destruction procedures for controlled substances are found in 21 CFR 1317.95. If the controlled substances are transferred to a person registered or authorized to accept a controlled substance for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any CS until transfer is complete. If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the transportation shall be directly to the registered location; 2 employees of the transporting registrant shall accompany the CS to the registered location. Load and unload or observe the loading and unloading of the CS until transfer is complete. If the CS are transported by a registrant to a destruction location that is not a registered location, the transportation shall be direct to the destruction location, 2 employees of the transporting registrant shall accompany the CS to the destruction location, load and unload or observe the loading and unloading of the CS; handle or observe the handling of any CS until	

	the substance is rendered non-retrievable; and personally witness the destruction of the CS until it is rendered non-retrievable. For onsite destruction, 2 employees of the registrant shall handle or observe the handling of any CS until the substance is rendered non-retrievable, and personally witness the destruction of the CS until it is rendered non-retrievable. It is recommended that this rule be changed to have subrule 1 pertain to noncontrolled substances and create another subrule to handle controlled substances. 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) 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. ~~**(54)**~~**(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.
Rules Committee Response	

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.~~

(**43**) 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.

Board Response	

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

Section Numbers	Commenter	Comment
(1)	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable clinic pharmacy is the licensee that possess the drugs not the charitable clinic.

		Suggested Change: Change the phrase "charitable clinic" to "charitable clinic pharmacy."
	Baran	Suggests deleting this rule. (For reasons stated in comment about R 338.3633).
Entire Rule	SIRUM	Letter of support for changes that require limited, specific information per form that are sufficient for efficiency and safety.
Rules Committee Response	(1) The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic. The committee requested that the department conduct research on to see if the language conflicted with the 21 CFR 1317 subpart B and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	This rule is required and cannot be deleted as the statute requires that participants in the program accept controlled substances for disposal. However, federal law requires that that a registrant complete DEA Form 41 and keep it for two years in accordance with 21 USC 827. It is recommended that the language be amended to encompass federal record keeping requirements for controlled substances. 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 DEA Form 41 and keep it for two years in accordance with 21 USC 827.
Rules Committee Response	

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.

Board Response	

Rule 338.3641 Transportation.

Section Numbers	Commenter	Comment
	Baran	Suggests deleting this rule. (For reasons stated in comment about R 338.3633).
Rules Committee Response	The committee requested that the department conduct research on to see if the language conflicted with the 21 CFR 1317 subpart B and report its findings. The decision on whether to edit the rule will be made pending research results.	
Research Results	This rule is required and cannot be deleted as the statute requires that participants in the program accept controlled substances for disposal. It is recommended to leave this rule unchanged.	

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.

Board Response	

Research on waivers, exceptions, or exemptions.

Section 585 of the DQSA states that states cannot establish or continue in effect any requirement for tracing products through the distribution system which are inconsistent with , more stringent , or in addition to, any requirements applicable under section 503(e) or which are inconsistent with any waiver, exception, or exemption pursuant to section 581 or 582.

So, there is no need to add that information in these rules.