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DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

MICHIGAN BOARD OF PHARMACY RULES COMMITTEE WORK GROUP MEETING

MINUTES AUGUST 1, 2023

The Michigan Board of Pharmacy Rules Committee Work Group met on August 1, 2023. The meeting was held via Zoom.

CALL TO ORDER

Stephanie Wysack, Board Support Technician, called the meeting to order at 9:04 a.m.

ATTENDANCE

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

Members Absent: Pierre Boutros, R.Ph.

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

Public Present: Rose Baran, Pharm.D.

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 public comments received during the open comment period for the public hearing held on July 13, 2023.

The following are comments submitted by Baran:

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

Section (1), (3), and (4): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

Discussion was held.

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Section (3)(a): The commenter requested language to clarify when article 15 applied and when article 17 applied.

Przybylo stated that pharmacies are licensed under article 15 so making a change would be appropriate. She suggested “The name, address, telephone number, and license number of the pharmacy, *or charitable clinic pharmacy licensed under article 15...*” and leave the rest of the rule as written.

Discussion was held.

The committee agreed to accept the comment and modify the language as suggested by Przybylo.

Section (4): The commenter stated that there was no need for a form as the rule outlined the necessary information.

Poynter stated that a form assisted with making sure that the listed information was submitted.

The committee rejected the comment, agreeing that a form assisted the entity in providing the required information.

R 338.3605 Eligible prescription drugs.

Section (2): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

Discussion was held.

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

R 338.3607 Ineligible drugs; controlled substances prohibited.

Section (1)(f): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Section (2): The commenter stated that a pharmacy donating a controlled substance to another pharmacy must comply with the Pharmacy- Controlled Substance Rules and follow the DEA regulations for transfer and disposal of controlled substances.

Sesi stated that following the federal law was a given and does not need to be referenced.

Discussion was held.

The committee rejected the comment, because controlled substances can be donated to an eligible facility and pharmacists know they must follow federal law as part of their protocols for disposal.

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

Title, and Sections (1) and (2): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Section (1)(c): The commenter provided language that included the lot number as required under the Food Drug and Cosmetic Act.

Baran clarified her comment. She stated that her comment referred to manufacturing labels, not individual prescription labels.

Sesi stated that the change should only be made if it was federally required. She requested that it be researched and discussed with the full board.

The committee agreed that the comment would be accepted if federally required, otherwise rejected as keeping the rule broad was clear.

Section (1)(e) and (f): The commenter requested that the term “misbranding” be added to clarify the complete history of the package.

The committee agreed that depending on the research for Section (1)(c), the comment would be accepted if Section (1)(c) was changed but rejected if not changed. This would be discussed with the full board.

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

Section (1) and (2): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy” and add pharmacy after eligible facility.

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

R 338.3615 Transfer and shipment of donated drugs; requirements.

Section (1): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy” and add pharmacy after eligible facility.

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

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

Sections (1) through (7): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

The commenter requested that the term “misbranding” be added to clarify the complete history of the package.

The committee agreed that depending on the research for Section (1)(c), the comment would be accepted if Section (1)(c) is changed but rejected if not changed. This would be discussed with the full board.

Section (8): The commenter requested that this rule be deleted as it was covered under federal law.

The committee agreed that depending on the research for Section (1)(c), the comment would be accepted if Section (1)(c) was changed but rejected if not changed. This would be discussed with the full board.

R 338.3621 Forms; general requirements.

Section (1): The commenter provided language to clarify that records could be stored with all other prescription records.

Baran clarified her comment.

Discussion held as to whether changing where the records were kept affected patient safety.

The committee rejected the comment as there was no impact to patient safety with the rule as written.

Sections (3) and (4): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

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

Sections (b), (c), and (e): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Baran clarified that her second comment on the rule in that the serialized transaction information was very specific in tracking the item from manufacturer to pharmacy and should be a requirement on the form.

The committee stated that research needed to be done to determine whether the serialized transaction information was required under the Drug Quality Security Act. If it was, then the language from the comment should be added, but if not, and it does not affect patient safety, then the comment should be rejected.

R 338.3621c Transfer form; requirements.

Title and section (b): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Baran’s second comment on the rule stated that the serialized transaction information was very specific in tracking the item from manufacturer to pharmacy and should be a requirement on the form.

The committee stated that research needed to be done to determine whether the serialized transaction information was required under the Drug Quality Security Act. If it was, then the language from the comment should be added, but if not, and it does not affect patient safety, then the comment should be rejected.

R 338.3621d Destruction form: requirements.

Section (a): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

R 338.3625 Dispensing donated prescription drugs; requirements.

Sections (1), (2), and (3): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

R 338.3627 Handling fee.

Sections (1) and (3): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Section (2): The commenter stated that this section was no longer needed because in subrule (1), the use of the Medicaid standard dispensing fee was deleted.

Przybylo confirmed that the commenter's statement was correct.

The committee agreed with the comment to remove this subrule.

R 338.3629 Donation to other participating pharmacy or charitable clinic.

Title and rule content: The commenter requested language be changed from "charitable clinic" to "charitable clinic pharmacy."

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

R 338.3631 Registry; creation.

Rule content: The commenter requested language be changed from "charitable clinic" to "charitable clinic pharmacy."

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

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

Sections (1), (2), (3), and (4): The commenter requested language be changed from "charitable clinic" to "charitable clinic pharmacy."

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

Collection device comment: The commenter provided language to add a reference to the federal rule to clarify disposal requirements.

Taylor stated that research needed to be done to determine the requirements for disposal under the federal rule.

The committee stated that this comment needed to be discussed with the full board, after research was completed on the federal rule for disposal requirements.

R 338.3635 Collection device; requirements.

Rule content: The commenter requested language be changed from "charitable clinic" to "charitable clinic pharmacy."

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

The commenter suggested that the rule be deleted as it conflicted with federal rule.

The committee stated that this comment needed to be discussed with the full board, after research was completed on the federal rule for disposal requirements.

R 338.3637 Access; destruction of collected drugs.

Section (2): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

The commenter suggested that the rule be deleted as it conflicted with federal rule.

The committee stated that this comment needed to be discussed with the full board, after research was completed on the federal rule for disposal requirements.

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

Section (1): The commenter requested language be changed from “charitable clinic” to “charitable clinic pharmacy.”

The committee elected not to make the suggested change to avoid confusion because the pharmacy must be part of the clinic.

The commenter suggested that the rule be deleted as it conflicted with federal rule.

The committee stated that this comment needed to be discussed with the full board, after research was completed on the federal rule for disposal requirements.

R 338.3641 Transportation

The commenter suggested that the rule be deleted as it conflicted with the federal rule.

The committee stated that this comment needed to be discussed with the full board, after research was completed on the federal rule for disposal requirements.

ADJOURNMENT

Przybylo stated that the proposed recommendations to the draft rules would be reviewed by the board at the August 25, 2023 meeting.

Przybylo adjourned the meeting at 9:56 a.m.

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

August 3, 2023

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	<p>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.</p> <p>Suggested Change: Change the phrase “charitable clinic” to “charitable clinic pharmacy.”</p>
(3)(a)	Baran	<p>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.</p> <p>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.</p>
(4)	Baran	<p>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.</p> <p>Suggested change: (4) A participating pharmacy or charitable clinic may withdraw from</p>

		<p>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:</p> <p>(a) Name, address, telephone number, and license number of the participating pharmacy or charitable clinic pharmacy.</p>
Rules Committee Response	<p>(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.</p> <p>(3)(a): The committee agreed that clarification was needed. The committee suggests 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.</p> <p>(4): The committee elected not to make this change as the department uses a form to ensure that all submissions contain the required information.</p>	

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 ~~license~~ **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 333.1775.**

(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	
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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	
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Rule 338.3607 Ineligible drugs; controlled substances prohibited.

Section Numbers	Commenter	Comment
(1)(f)	Baran	<p>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.</p> <p>Suggested Change: Change the phrase “charitable clinic” to “charitable clinic pharmacy.”</p>
(2)	Baran	<p>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) <i>"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.</i>” 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.</p> <p>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.</p>
Entire rule	SIRUM	<p>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.</p>
Rules Committee Response		<p>(1)(f): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.</p> <p>(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.</p>

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 of 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	
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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	<p>21 CFR 201.18 requires a lot number on prescription drugs. <i>“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.”</i></p> <p>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. <i>“A drug or device shall be deemed to be misbranded . . .if its labeling is false or misleading in any particular.”</i> See 21 USC 352 of the Federal Food, Drug and Cosmetic Act (page 143 of link).</p> <p>Effective November 27, 2023, pharmacies must comply with the Drug Supply Chain Security Act, Public Law 113-54. (<i>Drug Supply Chain Security Act is Title II page 13 of link</i>). 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.</p> <p>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.</p>
(1)(e) and (f)	Baran	<p>21 CFR 201.18 requires a lot number on prescription drugs. <i>“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.”</i></p> <p>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</p>

		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	<p>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.</p> <p>(1)(c): The committee requested that the department conduct research on this suggestion and report its findings at the next board meeting. The decision on whether to edit the rule will be made pending research results.</p> <p>(1)(e) and (f): The committee requested that the department conduct research on this suggestion and report its findings at the next board meeting. The decision on whether to edit the rule will be made pending research results.</p>	
Research Results		

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.

Board Response	
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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.

Rule 338.3615 Transfer and shipment of donated drugs; requirements.

Section Numbers	Commenter	Comment
(1)	Baran	<p>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.</p> <p>Suggested Change: Change the phrase “charitable clinic” to “charitable clinic pharmacy.”</p>
(1)	Baran	<p>Add pharmacy to eligible facility, as an eligible facility without a pharmacy may not possess drugs.</p> <p>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.</p> <p>(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.</p>
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.

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

Board Response	
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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 at the next board meeting. 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 at the next board meeting. The decision on whether to edit the rule will be made pending research results.
Research Results	

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 ~~as per~~ 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	
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Rule 338.3621 Forms; general requirements.

Section Numbers	Commenter	Comment
(1)	Baran	<p>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.</p> <p>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.</p>
(3) and (4)	Baran	<p>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.</p> <p>Suggested Change: Change the phrase “charitable clinic” to “charitable clinic pharmacy.”</p>
Rules Committee Response	<p>(1): The committee elected not to make the suggested change because keeping these files separate does not impact patient safety.</p> <p>(2) and (4): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.</p>	

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.~~

(61) 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.**

(72) 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	
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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	(b), (c and (e): The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part	

Response	of the clinic. The committee requested that the department conduct research on adding language from the DQSA and report its findings at the next board meeting. The decision on whether to edit the rule will be made pending research results.
Research Results	

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.

Board Response	
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Rule 338.3621c Transfer form; requirements.

Section Numbers	Commenter	Comment
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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 at the next board meeting. The decision on whether to edit the rule will be made pending research results.	
Research Results		

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) 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) 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.

Board Response	
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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 or NDC number.
 - (iii) The quantity and strength of the drug.

Board Response	
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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.

(32) 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**.

(43) **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	
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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 recommends 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/mdeh/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	
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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	
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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 ~~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	
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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	<p>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.</p> <p>Suggested Change: Change the phrase “charitable clinic” to “charitable clinic pharmacy.”</p>
	Baran	<p>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.</p> <p>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.</p> <p>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</p>

		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 on to see if the language conflicted with the 21 CFR 1317 subpart B and report its findings at the next board meeting. The decision on whether to edit the rule will be made pending research results.	
Research Results		

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~~ **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	
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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 the 21 CFR 1317 subpart B and report its findings at the next board meeting. The decision on whether to edit the rule will be made pending research results.	
Research Results		

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 satisfy 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	
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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 at the next board meeting. The decision on whether to edit the rule will be made	

	pending research results.
Research Results	

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.

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

Board Response	
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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	<p>(1) The committee elected not to make the suggested change to avoid confusion as the pharmacy must be part of the clinic.</p> <p>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 at the next board meeting. The decision on whether to edit the rule will be made pending research results.</p>	
Research Results		

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	
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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 at the next board meeting. The decision on whether to edit the rule will be made pending research results.	

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	
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