MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
OCTOBER 30, 2023

The Michigan Board of Pharmacy Rules Committee Work Group met on October 30, 2023. The meeting was held via Zoom.

CALL TO ORDER

Kerry Przybylo, JD, Manager, called the meeting to order at 9:00 a.m.

ATTENDANCE

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

Members Absent: None

Staff Present: 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

RULES DISCUSSION

Przybylo explained that today's meeting will involve reviewing the public hearing comments for the Program for Utilization of Unused Prescription Drugs MOAHR #2022-62 LR and Controlled Substances MOAHR #2022-06 rule sets.

Pharmacy – Program of Utilization of Unused Prescription Drugs # 2022 62 LR - Public Comment Summary (A copy of the draft, pursuant to today's discussion, is attached)

Przybylo stated that the committee would review the research conducted, related to the public comments received for the public hearing held on July 13, 2023. She stated that the Michigan Office of Administrative Hearings and Rules (MOAHR) stated that the rules would have to go to a hearing again, due to required changes needed under the Drug Supply Chain Security Act (DSCSA).

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

Subrule (8): Przybylo revisited this subrule stating that the committee had rejected the comment to delete the section. However, further research was completed and clarifying language was added to make clear that this subrule is subject to federal and state laws and rules.

Przybylo further stated that since this set is going to rehearing, she accepted a comment from SIRIUM that provided clarifying language for **subrule 4** stating that the subrule content included unused prescription drugs that met eligibility requirements for distribution upon receipt but were subsequently not dispensed to an eligible patient under the program.

The committee agreed with the suggested language as presented.

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

Przybylo stated that the committee had requested that the transaction history be removed. She indicated that the department advised that this should not be omitted because that the information needed to remain in the rule until the DSCSA went into effect.

Przybylo provided language, as new R 338.3621a(f), that referenced requirements of the DSCSA, to keep the rule broad.

The committee agreed with the new language as presented.

R 338.3621c Transfer form; requirements.

Section (a): Przybylo stated that the transaction requirements list came directly from the DSCSA.

Przybylo provided language to reference the DSCSA, as new R 338.3621c(e), instead of separately listing the requirements.

The committee agreed to new language as presented.

Przybylo stated that the committee requested clarification on the need to reference “serial number.” She indicated that the department advised that the information is required under federal law.

Przybylo suggested the use of “product identifier” as defined by DSCSA.

Discussion held.

The committee agreed to the use of “product identifier” instead of “serial number” as it was more general.

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

Section (1): Przybylo stated that a statement mandating that the disposal of prescription drugs comply with federal law requirements should be added. The committee had asked for research to be done to determine whether the language provided, conflicted with 21 CFR part 1317 subpart B.

Przybylo stated that research indicated that a collection device needed to be available, for drugs that cannot be dispensed through the program. She provided suggested language to clarify the rule to accommodate both the statute and 21 CFR Part 1317 subpart B.

The committee agreed with the language as presented.

R 338.3635 Collection device; requirements.

Przybylo stated that language had been added to clarify the rule applied to ineligible drugs.

The committee agreed with the language as presented.

R 338.3637 Access; destruction of collected drugs.

Section (2): Comment from Baran requested that the rule be deleted.

Przybylo stated that the rule had been reorganized and language had been added to clarify the rule was for ineligible drugs.

The committee rejected the comment to delete the rule and agreed with the rule edits as presented.

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

Section (1): Comment from Baran requested that the rule be deleted.

Przybylo stated that the rule needed to stay to provide clarification on record keeping. Research showed that the DEA required the retention of DEA Form 41 for 2 years. She provided suggested language.

The committee rejected the comment to delete the rule and agreed with the language as presented.

R 338.3641 Transportation.

Comment from Baran requested that the rule be deleted.

Przybylo stated that the rule needed to stay to provide information regarding transportation.

The committee rejected the comment to remove the rule.

Przybylo stated that SIRUM had provided language after the last Rules Committee Work Group, regarding waivers, that could be applied to these rules. She stated that language in the DSCSA covers waivers and that adding anything additional to the rules could cause confusion.

The committee agreed with Przybylo to not include a new section to cover waivers specifically.

Pharmacy – Controlled Substances - Public Comment Summary (A copy of the draft, pursuant to today's discussion, is attached)

R 338.3102 Definitions I to P.

Subrule d: Comment from Baran to change the ASAP standard from 4.1 to 5.0.

Przybylo stated that ASAP 5.0 does not go into effect until January 1, 2024 and that the Administrative Procedures Act does not allow for adoption of future standards. She suggested changing the standard and waiting until after the first of the year to move the rules forward.

Discussion held.

The committee agreed with the comment and to hold the rules until after January 1, 2024, allowing for the new standard to be referenced.

Subrule f: Comment from Baran stated that the Code of Federal Regulations definition of NDC does not include “vendor”, so it should be removed.

Przybylo verified that the comment was correct.

The committee agreed with the comment to remove “vendor.”

Subrule (h)(iv): Comment from Baran to clarify the type of identification a resident of a tribal nation my obtain. She provided suggested language.

The committee agreed with the comment and to use the suggested language provided.

R 338.3111 Schedules; federal controlled substance schedules adopt by reference; exceptions.

Chludzinski comment: The comment inquired why the drug was being removed from the schedule when it poses potential harm.

The committee stated that Michigan is in the minority with scheduling this drug. It was scheduled to reduce prescribing amounts and that has not changed with the scheduling. This drug is widely used, and the scheduling creates difficulty for the prescribers, the pharmacists, and the patients in receiving the drug.

The committee rejected the comment to remove the scheduling for the above stated reasons.

Subrule (3)(d): Comment from O’Connor that the definition of isomers was confusing. Suggested removing “…., which includes the optical, position, and geometric isomers.” from the end.

Discussion was held.

The committee agreed with the commenter to remove the suggested language.

R 338.3132 Controlled substance license.

Sections (5) and (7): Comment from O’Connor stating that there were revisions to the protocol required for licensure for controlled substance research and analytical labs. References to some of the CFR’s are not needed as these do not apply and the inclusion causes confusion.

Suggested language was provided.

Taylor stated that if all the requirements were covered, she agreed with the suggestion.

Przybylo stated that department staff verified the information.

The committee agreed with the comment and the suggested change provided.

R 338.3135 Opioids and other controlled substances awareness training standards for prescribers and dispensers of controlled substances; requirements.

Sections (1), (2), and (5): Comment from O'Connor to allow the federal requirements for training in substance abuse to count toward state requirements. Suggested changes provided.

Przybylo pointed out that training in MAPS and state law were still listed.

Discussion was held.

The committee agreed with the comment and the suggested change as provided.

R 338.3141 Thefts and diversions.

Subrule 3: Comment from Baran stating that the time frame in the rules differs from the time frame given by the DEA.

Przybylo confirmed that the comment was correct, and that the DEA gives 45 days, while the rules currently state 15 days.

The committee agreed with the comment and to change to 45 days.

R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.

Subrule 3: Comment from Baran stating that the DEA requires controlled substance prescriptions to be kept on site, therefore "on site" should not be deleted from the rule.

Sesi stated that if keeping the prescriptions on site is a requirement of the CFR, then it should remain in the rule.

The committee agreed with the comment to leave "on site" in the rule.

Subrule 6: Comment from Baran to delete the subrule as it is already covered under a previous rule.

Discussion held.

The committee agreed with the comment to delete the subrule.

R 338.3161 Controlled substance prescriptions.

Section (1)(b) and (6): Comment from Chludzinski stated that the rules are conflicting as to how a prescriber is identified and that clarification is needed.

Section (6): Comment from Baran also stated that the language is unclear as to how the prescriber information is stored. She provided suggested language.

Sesi suggested removing section (6) and adding language to (1)(b) for clarification.

Discussion was held.

Przybylo suggested the additional language to section (1)(b) read "…. pager number, and professional designation that is either written on the prescription or stored in the pharmacy's automated data processing system."

The committee agreed with both comments and to provide clarification by removing section (6) and adding Przybylo's suggested language to section (1)(b).

R 338.3162a Electronic transmission of prescription; waiver of electronic transmission.

Comment from Baran stated that R 333.17754 no longer applies and should be changed to R 333.17754a.

Przybylo stated that the rule was written prior to the rule going into effect on January 1, 2023. She provided updated language to sections (1) and (3) that reference the effective date.

The committee agreed with the comment and the new language as presented, not referencing a separate rule.

ADJOURNMENT

Przybylo stated that the Pharmacy - Program of Utilization of Unused Prescription Drugs draft would go to another public hearing due to the statutory changes made. She stated

the Pharmacy - Controlled Substance public comment recommendations will go to the Board for a vote on December 20, 2023.

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

Prepared by:
Stephanie Wysack, Board Support Technician October 31, 2023
Bureau of Professional Licensing

Pharmacy – Program of Utilization of Unused Prescription Drugs – MOAHR #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	Sirum subsequently suggested adding the following to subrule 4: **This subrule includes unused prescription drugs that met eligibility requirements for distribution upon receipt but were subsequently not dispensed to an eligible patient under the program.** The committee agreed with the changes suggested by the department and SIRUM.

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

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

(2) The participating pharmacy or charitable clinic shall store donated drugs ~~pursuant to~~ **under** the manufacturer's guidelines or ~~usp-nf~~ **USP-NF** guidelines. Donated drugs ~~shall~~ **must be stored and maintained in a manner that distinguishes them physically or electronically from other non-donated inventory.** ~~not be stored with non-donated inventory at any time.~~

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

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

(5) A participating pharmacy or charitable clinic shall create and maintain a destruction and disposal record for donated **prescription** drugs that are destroyed and disposed of as a result of being expired, adulterated, recalled, or otherwise not eligible for dispensing. A participating pharmacy or charitable clinic shall maintain a destruction record for 5 years after destruction of the donated drugs. **Two years after the destruction of the donated drugs, the participating pharmacy or charitable clinic may make an electronic duplicate of the original record that becomes the original record. A participating pharmacy or charitable clinic shall present a paper copy of the electronic duplicate to an authorized agent of the board on request.**

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

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

(8) Notwithstanding any state or federal 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.

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	(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. 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 complies with the requirements of the Drug Supply Chain Security Act, 21 USC 351 *et seq*, or is subject to a wavier, exemption, or exception by the FDA.**
Rules Committee Response	The committee agreed with the suggested changes recommended by the department because until the DSCSA is in full effect because each transaction going back to the manufacturer must be available in the event of a recall or investigation.

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 complies with the requirements of the Drug Supply Chain Security Act, 21 USC 351 *et seq*, or is subject to a wavier, exemption, or exception by the FDA.

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 from the DSCSA 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 product identifier.** ~~(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 this transaction complies with the requirements of the Drug Supply Chain Security Act, 21 USC 351 et seq, or is subject to a wavier, exemption, or exception by the FDA.
Rules Committee Response	The committee agreed with the suggested changes post research.

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 product identifier.

~~(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 from the donating entity stating that this transaction complies with the requirements of the Drug Supply Chain Security Act, 21 USC 351 *et seq*, or is subject to a wavier, exemption, or exception by the FDA.

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**.

(**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	

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	Baran	By definition in, MCL 333.17775, a charitable clinic "has a licensed pharmacy." The charitable

(4)		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	The committee approved of the suggested changes post research.

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

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

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

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

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

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 **upon receipt** are ineligible for distribution under the program for destruction and disposal that meets all ~~of~~ the following ~~criteria~~ **requirements**: (a) Is designed to allow **prescription drugs and other medications to be added to the device but allow only authorized personnel to remove the** contents **from the collection device** ~~to be added to the device but not removed, except by authorized personnel~~ for ~~the purpose of~~ destruction and disposal. (b) **Is securely fastened to a permanent structure.** **(c) Is a tamper resistant, securely locked, substantially constructed container with a permanent outer container and a removable inner liner.** ~~(b)~~**(d)** Is labeled ~~pursuant to~~ **consistent with** all applicable state and federal laws and regulations~~.~~ **and includes the following statements prominently displayed on the collection device, and also in another location near the collection device:** **(i) "Controlled substances cannot be accepted for destruction and disposal, unless allowed under federal law."** **(ii) "Chemotherapeutic agents must not be placed in this collection device."** ~~(c)~~**(e)** Is lined with a removable liner that is waterproof, tamper-evident, tear resistant, and capable of being sealed. ~~(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	The committee agreed with the suggested changes.

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

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

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

(b) Is securely fastened to a permanent structure.

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

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

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

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

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

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

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

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

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

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

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

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

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. ~~(5)~~**(d)** The contents of the collection device ~~shall~~ **must** be destroyed ~~pursuant to~~ **under** all applicable state and federal laws and regulations. **(2) For controlled substances, destruction procedures under federal law must be followed pursuant to 21 CFR 1317.95.**
Rules Committee Response	The committee agreed with the suggested changes post research.

R 338.3637 Access; destruction of collected drugs.

Rule 37. 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.

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

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

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	The committee agreed with the suggested changes post research.

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.

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.	
Rules Committee Response	The committee agreed not to make the suggested edits as this rule is required.	

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.

Pharmacy - Controlled Substances – MOAHR #2022-06 LR
Public Comment Summary

Testimony/Comments Received:

Baran, Rose, Pharm D
Chludzinski, Paul, RPh, Pharmacy Regulatory Specialist, Henry Ford Hospital
O'Connor, Martha

Rule 338.3102 Definitions I to P.

Section Numbers	Commenter	Comment
Subrule d	Baran	ASAP 4.1 Standard is outdated. The current Standard is 4.2B. The 2023 version 5.0 to be implemented January 2024. **Suggested Change:** MAPS claim form "means a form, determined by the department~~,~~ that is in the format and includes the information as specified by the ASAP 5.0 Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b."
Subrule f	Baran	The definition in the Code of Federal Regulations 21 USC 207.33(a) does not have vendor. "The NDC for a drug is a numeric code. Each finished drug product or unfinished drug subject to the listing requirements of this part must have a unique NDC to identify its labeler, product, and package size and type." Suggested Change: Delete vendor in the definition.
Subrule (h)(iv)	Baran	Residents of a tribal nation may only have a tribal government issued identification. To make it clear that a tribal government issued identification can be used for MAPS. **Suggested Change:** Add (D) to 338.3102(**h**)(iv)(D) A tribal government identification number obtained from a tribal government issued identification.
Rules Committee Response	Subrule d: The committee agreed with the suggested changes. Subrule f: The committee agreed with the suggested changes.	

	Subrule (h)(iv) The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.

R 338.3102 Definitions; I to P.

Rule 2. As used in these rules:

(a) "Inventory" means all stocks in finished form of a controlled substance that are manufactured or otherwise acquired by a licensee, whether in bulk or commercial containers or contained in pharmaceutical preparations in the possession of the licensee.

(b) "Licensee" means a person ~~who~~ **that** is licensed ~~pursuant to~~**under** section 7303 of the code, MCL 333.7303.

(c) "MAPS" means the Michigan automated prescription system.

(~~c~~**d**) "~~Michigan automated prescription system (~~MAPS~~)~~ claim form" means a form, ~~to be~~ determined by the department~~,~~ that is in the format and includes the information as specified by the ~~American Society for Automation in Pharmacy (~~ASAP~~)~~ ~~4.1~~ **5.0** Standard for Prescription Drug Monitoring Programs and contains the information specified in R 338.3162b.

(e) "Medical institution" means that term as defined in R 338.486.

(~~d~~**f**) **"NDC" means a** ~~National~~ **national** drug code number ~~(NDC)" means a number~~ that identifies the labeler, ~~vendor,~~ product, and package size and is assigned to each drug product listed under section 510 Registration of Producers of Drugs and Devices, of the ~~Federal Food, Drug, and Cosmetic Act (~~FDCA**,** ~~) of 2017, 21 USC 360~~**21 USC 360.**

(~~e~~**g**) "Officer" means a federal, state, county, or local law enforcement officer who enforces the laws of this state.

(~~f~~**h**) "Patient identifier" means all of the following information about a patient:

(i) Full name.

(ii) Address, including zip code.

(iii) Date of birth.

(iv) ~~Any 1~~**One** of the following identification numbers:

(A) A state-issued driver's license number obtained from a state-issued driver's license.

(B) A state-issued identification number obtained from a state-issued photo identification card.

(C) A federal passport number obtained from a federal passport.

(D) A tribal government identification number obtained from a tribal government issued identification.

~~The number zero. Zeroes must be entered as the identification number, if the positive identification presented for the patient or client does not include a license number, identification number, or passport number as listed in subparagraphs (A) to (C) of this paragraph, the patient is under the age of 16, or the animal's owner cannot be identified.~~

(E) The number zero. Zeroes must be entered as the identification number, if the positive identification presented for the patient or client does not include a license number, identification number, or passport number as listed in subparagraphs (A) to (C) of this paragraph, the patient is under the age of 16, or the animal's owner cannot be identified.

(g**i**) "Positive identification" means identification that includes a photograph of an individual in addition to ~~his or her~~**the individual's** date of birth. Positive identification includes an identification card issued by a governmental agency~~, if the identification card meets the requirements of this rule~~.

~~(h) "Medical institution" means the term as defined in R 338.486.~~

~~(i) "Pharmacy services" means the direct and indirect patient care services associated~~ ~~with the practice of pharmacy, as defined in section 17707 of the code, MCL 333.17707.~~

Board Response	

Rule 338.3111 Schedules; federal controlled substance schedules adopt by reference; exceptions.

Section Numbers	Commenter	Comment
Removal of Gabapentin from the schedule	Chludzinski	Regarding the proposal to remove gabapentin as a Schedule 5 drug (R338.3111) to align with the federal scheduling and the majority of the states in the Great Lakes Region: If the Public Health Code requires the board to schedule a substance if it has a potential for abuse (333.7203), and gabapentin presents a potential for abuse, shouldn't it remain a scheduled drug in Michigan? • *Gabapentin Presents High Potential for Misuse* (November 2022). https://www.pharmacytimes.com/view/gabapentin-presents-high-potential-for-misuse • *Gabapentin Abuse Potential* (June 2023), https://americanaddictioncenters.org/neurontin-abuse
3(d)	O'Connor	Subrule (3)(d) pertains to the definition of isomers. It needs clarification to avoid confusion with the chart. **Suggested language:** **(d) Isomers:**

		The definition of the term “isomer” used in 21 CFR 1308.11, schedule 1, is modified to include any optical, positional, or geometric isomer. The definition of “isomer” used in 21 CFR 1308.12 to 1308.15, schedules 2 to 5, remains as set forth in 21 CFR 1300~~, which includes the optical, position, and geometric isomers~~.
Rules Committee Response	The committee stated that Michigan is in the minority with scheduling this drug. It was scheduled to reduce prescribing amounts and that has not changed with the scheduling. This drug is widely used, and the scheduling creates difficulty for the prescribers, the pharmacists, and the patients in receiving the drug. The committee wanted to continue forward with the removal of this drug from scheduling. Subrule 3(d): The committee agreed with the suggested change. Rule edits per the committee’s suggestion are in red below.	

R 338.3111 Schedules; federal controlled substance schedules adopt by reference; exceptions.

Rule 11. (1) The board approves and adopts by reference the complete list of drugs and other substances that are considered controlled substances under the ~~Controlled Substance Act (~~CSA~~)~~ ~~of 1970, 21 USC 801~~, that have been divided into 5 schedules as published in 21 CFR 1308.11 to 1308.15, except for **the following:**

(a) ~~those drugs~~**Drugs** or other substances ~~specifically~~ **scheduled, rescheduled, or descheduled** ~~excepted~~ by this state’s laws enacted after ~~the effective date of these rules~~**January 6, 2022.** ~~or as~~

(b) Drugs listed in subrule (3) of this rule**, which are scheduled differently than scheduled in 21 CFR 1308.11 to 1308.15**.

(2) The standards adopted by reference in subrule (1) of this rule are available at no cost at ~~https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm~~ **https://www.ecfr.gov/current/title-21/chapter-II/part-1308**, or at 10 cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.

(3) The following drugs and other substances are ~~scheduled~~**designated as a schedule 1, 2, 3, 4, or 5 drug,** as follows:

Drug or Substance	**1**	**2**	**3**	**4**	**5**
(a) Synthetic cannabinoid: **Includes a material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules 2 to 5, is not approved by the FDA as a drug, and contains a quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs),**	**x**				

and salts of isomers and homologues (analogs), unless specifically excepted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation: **(i) A compound containing a 3-(1-naphthoyl)indole structure, also known as napthoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-007, JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, JWH-398, AM-1220, AM-2201, and WIN-55, 212-2.** **(ii) A compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure, also known as napthylmethylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-175 and JWH-184.** **(iii) A compound containing a 3-(1-naphthoyl)pyrrole structure, also known as naphthoylpyrroles with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2- piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the pyrrole ring to an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-370 and JWH-030.** **(iv) A compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indene ring to an extent and whether or not substituted on the naphthyl ring to an extent. Examples of this structural class include, but are not limited to, JWH-176.** **(v) A compound containing a 3-phenylacetylindole structure, also known as phenacetylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to an extent and whether or not substituted on the phenyl ring to an extent. Examples of this structural class include, but are not limited to, RCS-8 (SR-18), JWH-250, JWH-203, JWH-251, and JWH-302.**					

(vi) A compound containing a 2-(3-hydroxycyclohexyl)phenol structure, also known as cyclohexylphenols, with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted on the cyclohexyl ring to an extent. Examples of this structural class include, but are not limited to, CP-47,497 (and homologues(analogs)), cannabicyclohexanol, and CP-55,940. **(vii) A compound containing a 3-(benzoyl)indole structure, also known as benzoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the indole ring to an extent and whether or not substituted on the phenyl ring to an extent. Examples of this structural class include, but are not limited to, AM-694, pravadoline (WIN-48,098), RCS-4, AM-630, AM-679, AM-1241, and AM-2233.** **(viii) A compound containing a 11-hydroxy-/\8-tetrahydrocannabinol structure, also known as dibenzopyrans, with further substitution on the 3-pentyl group by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkyethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group. Examples of this structural class include, but are not limited to, HU-210, JWH-051, JWH-133.** **(ix) A compound containing a 3-(1-adamantoyl)indole structure, also known as adamantoylindoles, with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted on the adamantyl ring system to an extent. Examples of this structural class include, but are not limited to, AM-1248.** **(x) A synthetic chemical compound that is a cannabinoid receptor agonist and mimics the pharmacological effect of naturally occurring cannabinoids that is not listed in schedules 2 through 5 and is not approved by the FDA as a drug.**					
(b) Synthetic cathinone: **Includes a material, compound, mixture, or preparation that is not otherwise listed as a controlled substance in this schedule or in schedules 2 through 5, is not approved by the FDA as a drug, and contains a quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs), and salts of isomers and homologues (analogs), unless specifically excepted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation:** **(i) A compound containing a 2-amino-1-propanone structure with substitution at the 1-position with a**	**x**				

monocyclic or fused polycyclic ring system and a substitution at the nitrogen atom by an alkyl group, cycloalkyl group, or incorporation into a heterocyclic structure. Examples of this structural class include, but are not limited to, dimethylcathinone, ethcathinone, and alpha-pyrrolidinopropiophenone. **(ii) A compound containing a 2-amino-1-propanone structure with substitution at the 1-position with a monocyclic or fused polycyclic ring system and a substitution at the 3-position carbon with an alkyl, haloalkyl, or alkoxy group. An example of this structural class includes, but is not limited to, naphyrone.** **(iii) A compound containing a 2-amino-1-propanone structure with substitution at the 1-position with a monocyclic or fused polycyclic ring system and a substitution at a position of the ring system with an alkyl, haloalkyl, halogen, alkylenedioxy, or alkoxy group, whether or not further substituted at a position on the ring system to an extent. Examples of this structural class include, but are not limited to, mephedrone, methylone, and 3-fluoromethylone.**					
(c) Ephedrine: **A salt of ephedrine, an optical isomer of ephedrine, a salt of an optical isomer of ephedrine, or a compound, mixture, or preparation containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine except for both the following:** **(i) A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is not included in schedule 5 if the drug product meets all of the following criteria:** **(A) May lawfully be sold over the counter without a prescription under federal law.** **(B) Is labeled and marketed in a manner consistent with the pertinent over-the-counter tentative final or final monograph.** **(C) Is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse.** **(D) Is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement.** **(E) The drug product is 1 of the following:** **(I) A solid dosage form, including, but not limited to, a soft gelatin caplet that combines as active ingredients not less than 400 milligrams of guaifenesin and not more than 25 milligrams of ephedrine per dose and is packaged in blister packs with not more than 2 tablets or caplets per blister.** **(II) An anorectal preparation containing not more than 5% ephedrine.** **(ii) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement**					**x**

meets all of the following criteria: **(A) Contains, per dosage unit or serving, not more than the lesser of 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids in applicable regulations adopted by the FDA and contains no other controlled substance.** **(B) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids.** **(C) Is packaged with a prominent label securely affixed to each package that includes all of the following:** **(I) The amount in milligrams of ephedrine in a serving or dosage unit.** **(II) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.** **(III) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use in applicable regulations adopted by the FDA.** **(IV) That improper use of the product may be hazardous to an individual's health.**					
(d) Isomers: **The definition of the term "isomer" used in 21 CFR 1308.11, schedule 1, is modified to include any optical, positional, or geometric isomer. The definition of "isomer" used in 21 CFR 1308.12 to 1308.15, schedules 2 to 5, remains as set forth in 21 CFR 1300~~, which includes the optical, position, and geometric isomers~~.**	**x**				
(e) Marijuana: **As that term is defined in section 3 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27953, and pharmaceutical-grade cannabis, as that term is defined in section 8105 of the code, MCL 333.8105, if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the code but only for the purpose of treating a debilitating medical condition, as that term is defined in section 3 of the Michigan Medical Marihuana Act, 2008 IL 1, MCL 333.26423, and as allowed under the code.**		**x**			
(f) Salvia divinorum: **All parts of the plant presently classified botanically as *Salvia divinorum*, whether growing or not; the leaves and seeds of that plant; an extract from a part of that plant; and every compound, salt, derivative, mixture, or preparation of that plant or its leaves, seeds, or extracts.**	**x**				
(g) Salvinorin A	**x**				
(h) Tianeptine sodium: **By whatever official, common, usual, chemical, or brand name designated.**		**x**			

(a) Marijuana including pharmaceutical-grade cannabis, as those terms are defined in parts 71 and 81 of the code, MCL 333.7101 to 333.7125 and MCL 333.8101 to 333.8119, is a schedule 2 controlled substance if it is manufactured, obtained, stored, dispensed, possessed, grown, or disposed of in compliance with the code and as allowed by federal authority but only for the purpose of treating a debilitating medical condition as that term is defined in section 3(b) of the Michigan medical marihuana act, 2008 IL 1, MCL 333.26423, and as allowed under the code.

(b) Tianeptine sodium by whatever official, common, usual, chemical, or brand name designated is a schedule 2 controlled substance.

(c) Gabapentin by whatever official, common, usual, chemical, or brand name designated is a schedule 5 controlled substance.

(d) Loperamide is not a scheduled controlled substance in this state.

(e) Pentazocine is a schedule 4 controlled substance.

(f) Brorphine is a schedule 1 controlled substance.

(g) Except in subdivision (h) of this subrule, ephedrine, a salt of ephedrine, an optical isomer of ephedrine, a salt of an optical isomer of ephedrine, or a compound, mixture, or preparation containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is included in schedule 5.

(h) A product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is not included in schedule 5 if the drug product meets all of the following criteria:

(i) May lawfully be sold over the counter without a prescription under federal law.

(ii) Is labeled and marketed in a manner consistent with the pertinent over-the- counter tentative final or final monograph.

(iii) Is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse.

(iv) Is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement.

(v) The drug product is 1 of the following:

(A) A solid dosage form, including, but not limited to, a soft gelatin caplet that combines as active ingredients not less than 400 milligrams of guaifenesin and not more than 25 milligrams of ephedrine per dose and is packaged in blister packs with not more than 2 tablets or caplets per blister.

(B) An anorectal preparation containing not more than 5% ephedrine.

(C) A food product or a dietary supplement containing ephedrine, if the food product or dietary supplement meets all of the following criteria:

(I) Contains, per dosage unit or serving, not more than the lesser of 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids in applicable regulations adopted by the Federal Food and Drug Administration (FDA) and contains no other controlled substance.

~~(II) Does not contain hydrochloride or sulfate salts of ephedrine alkaloids.~~
~~(III) Is packaged with a prominent label securely affixed to each package that includes all of the following:~~
~~(1) The amount in milligrams of ephedrine in a serving or dosage unit.~~
~~(2) The amount of the food product or dietary supplement that constitutes a serving or dosage unit.~~
~~(3) That the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use in applicable regulations adopted by the FDA.~~
~~(4) That improper use of the product may be hazardous to an individual's health.~~

Board Response	

Rule 338.3132 Controlled substance license.

Section Numbers	Commenter	Comment
(5) and (7)	O'Connor	There are revisions to the protocol required for licensure for CS research and analytical labs. References to some of the CFR's are not needed as these do not apply and the inclusion causes confusion. The suggested edits are below to eliminate confusion of what is required: (5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with ~~his or her~~**the** application required under subrule (1) of this rule: (a) The applicant's credentials to conduct the proposed research. (b) The protocol and description of the nature of the proposed research that **contains the following information:** ~~is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~: **(i) Investigator:** **(a) Name, address, and DEA registration number, if any.** **(b) Institutional affiliation.** **(c) Qualifications, including a curriculum vitae and an appropriate list of publications.** **(ii) Research project:** **(a) Title of project.** **(b) Statement of the purpose.** **(c) Name of the controlled substance or substances involved and the amount of each needed.** **(d) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.** **(e) Location where the research will be conducted.**

		(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143 and for dispensing the controlled substances in order to prevent diversion. **(g) If the investigator desires to manufacture any controlled substance, a statement of the quantity to be manufactured and the sources of the chemicals to be used.** **(iii) Authority:** **(a) Institutional approval.** **(b) Approval of a Human Research Committee for human studies.** **(c) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).** **(d) Indication of an approved funded grant (number), if any.** (7) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information with ~~his or her~~**the** application required under subrule (1) of this rule: (a) The applicant's credentials to conduct the proposed chemical analysis. (b) The protocol and description of the nature of the chemical analysis that **contains the following information:** ~~is filed and approved by the FDA and the DEA pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~ **(i) Investigator:** **(a) Name, address, and DEA registration number, if any.** **(b) Institutional affiliation.** **(c) Qualifications, including a curriculum vitae and an appropriate list of publications.** **(ii) Chemical analysis project:** **(a) Title of project.** **(b) Statement of the purpose.** **(c) Name of the controlled substance or substances involved and the amount of each needed.** **(d) Description of the chemical analysis and instructional activity to be conducted, and the duration of the project.** **(e) Location where the chemical analysis will be conducted.** **(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143.** **(g) If the investigator desires to manufacture any controlled substance for analytical or instructional purposes, a statement of the quantity to be manufactured and the sources of the chemicals to be used.** **(iii) Authority:** **(a) Institutional approval.** **(b) Approval of a Human Research Committee for human studies.** **(c) Indication of an approved funded grant (number), if any.**

Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.

R 338.3132 Controlled substance license.

Rule 32. (1) A person ~~who~~ **that** manufactures, distributes, prescribes, or dispenses a controlled substance in this state or ~~who~~ proposes to engage in the manufacture, distribution, prescribing, or dispensing of a controlled substance in this state shall apply for a controlled substance license by submitting to the department a completed application on a form provided by the department along with the ~~requisite~~ **required** fee.

(2) In addition to meeting the requirements of section 7303 of the code, MCL 333.7303, an applicant's license ~~shall~~**must** be verified by the licensing agency of ~~any~~**a** state ~~of the United States in which~~ **where** the applicant holds or has ever held a controlled substance license. This includes, but is not limited to, showing proof of ~~any~~ disciplinary action taken or pending against the applicant.

(3) Except as otherwise provided in subrules (8) and (9) of this rule, a separate controlled substance license is required in each of the following circumstances:

(a) For each principal place of business or professional practice where the applicant stores, manufactures, distributes, prescribes, or dispenses controlled substances.

(b) Manufacturing and distributing a controlled substance **listed** in schedules 2-5. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to manufacture a controlled substance listed in schedules 2 to 5 may also conduct chemical analysis and research with a substance that is listed in the schedules under the same controlled substance license.

(c) Dispensing a controlled substance listed in schedules 2 to 5. A prescriber or practitioner who is licensed in this state to prescribe or dispense controlled substances listed in schedules 2 to 5 may also prescribe, dispense, administer, and conduct research with those substances under the same controlled substance license.

(d) Conducting research and instructional activity with a controlled substance listed in schedule 1. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to conduct research with controlled substances listed in schedule 1 may do both of the following:

(i) Manufacture the specific substances as set forth in the research protocol that is **submitted to the department with the application for licensure and** filed and approved by the FDA and the DEA ~~pursuant to~~**under** ~~the provisions of~~ 21 CFR 1301.18 ~~and submitted to the department with the application for licensure~~.

(ii) Distribute the specific substances to others who are licensed by this state to conduct research or chemical analysis with the schedule 1 substances.

(e) Conducting research with a controlled substance listed in schedules 2 to 5. An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity ~~who~~ **that** is licensed in this state to conduct research with the controlled substances listed in schedules 2 to 5 may also participate in all of the following activities:

(i) Conduct chemical analysis with the specific substances listed in those schedules.

(ii) Manufacture the specific substances if, and to the extent that, the manufacture of the specific controlled substances is set forth in a statement filed with the application for licensure.

(iii) Distribute the specific substances to others ~~who~~ **that** are licensed in this state to conduct research, chemical analysis, or instructional activity with the substances.

(iv) Conduct instructional activities with the specific substances.

(f) Conducting instructional activities with a specific controlled substance listed in schedules 2 to 5.

(g) Conducting chemical analysis with a controlled substance listed in ~~any~~**a** schedule**.** An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity that is licensed in this state to conduct chemical analysis with all controlled substances may manufacture the substances for analytical or instructional purposes, distribute the substances to others ~~who~~ **that** are licensed to conduct chemical analysis, instructional activity or research with the substances, and conduct instructional activities with the substances.

(h) A pharmacy stocking patient medication in an automated device located at an affiliated hospital location ~~pursuant to~~**under** section 17760 of the code, MCL 333.17760, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility**,** as **that term is** defined in section 20109 of the code, MCL 333.20109. The pharmacy responsible for the device shall obtain an additional controlled substance license for each location. If substances are stored at a health facility without an onsite pharmacy or an automated device stocked by a pharmacy, a designated prescriber shall obtain a controlled substance license **for the address where the drugs are stored**. **If a controlled substance is stored in an emergency kit, a controlled substance license solely for the emergency kit is not required by this rule.**

(4) An applicant shall obtain a separate controlled substance license for each practitioner license issued under article 15 of the code, MCL 333.16101 to 333.18838. The controlled substance license must be renewed ~~when~~**if** the **license issued under** article 15 ~~license~~ **of the code, MCL 333.16101 to 333.18838** is renewed and the controlled substance license is renewed for an equal number of years ~~as the article 15 license~~.

(5) An applicant who intends to conduct research involving controlled substances shall submit all of the following with ~~his or her~~**the** application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed research.

(b) The protocol and description of the nature of the proposed research that **contains the following information:**~~is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~ ~~i~~

(i) Investigator:

(a) Name, address, and DEA registration number, if any.

(b) Institutional affiliation.

(c) Qualifications, including a curriculum vitae and an appropriate list of publications.

(ii) Research project:

(a) Title of project.

(b) Statement of the purpose.

(c) Name of the controlled substance or substances involved and the amount of each needed.

(d) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(e) Location where the research will be conducted.

(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143 and for dispensing the controlled substances in order to prevent diversion.

(g) If the investigator desires to manufacture any controlled substance, a statement of the quantity to be manufactured and the sources of the chemicals to be used.

(iii) Authority:

(a) Institutional approval.

(b) Approval of a Human Research Committee for human studies.

(c) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).

(d) Indication of an approved funded grant (number), if any.

(c) A list of the controlled substances and doses to be used.

(6) An applicant who intends to conduct instructional activity involving controlled substances shall submit all of the following information with ~~his or her~~ **the** application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed instructional activity.

(b) A course outline for the proposed instructional activity.

(c) A list of the controlled substances and doses to be used.

(7) An applicant who intends to conduct chemical analysis involving controlled substances shall submit all of the following information with ~~his or her~~**the** application required under subrule (1) of this rule:

(a) The applicant's credentials to conduct the proposed chemical analysis.

(b) The protocol and description of the nature of the chemical analysis that **contains the following information:** i~~s filed and approved by the FDA and the DEA pursuant to~~**under** ~~the provisions of 21 CFR 1301.18.~~

(i) Investigator:

(a) Name, address, and DEA registration number, if any.

(b) Institutional affiliation.

(c) Qualifications, including a curriculum vitae and an appropriate list of publications.

(ii) Chemical analysis project:

(a) Title of project.

(b) Statement of the purpose.

(c) Name of the controlled substance or substances involved and the amount of each needed.

(d) Description of the chemical analysis and instructional activity to be conducted, and the duration of the project.

(e) Location where the chemical analysis will be conducted.

(f) Statement of the security provisions for storing the controlled substances in accordance with R 338.3143.

(g) If the investigator desires to manufacture any controlled substance for analytical or instructional purposes, a statement of the quantity to be manufactured and the sources of the chemicals to be used.

(iii) Authority:

(a) Institutional approval.

(b) Approval of a Human Research Committee for human studies.

(c) Indication of an approved funded grant (number), if any.

(c) A list of the controlled substances and doses to be used.

(8) A prescriber or practitioner who is licensed in this state to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations is not required to obtain a separate controlled substance license for each additional physical location of the business or professional practice if the prescriber or practitioner only prescribes controlled substances at each additional physical location of the business or professional practice.

(9) A pharmacist shall maintain 1 controlled substance license in this state to dispense from ~~any~~**a** licensed pharmacy in this state.

Board Response	

Rule 338.3135 Opioids and other controlled substances awareness training standards for prescribers and dispensers of controlled substances; requirements.

Section Numbers	Commenter	Comment
(1), (2), (5)	O'Connor	Due to the federal requirement of 8 hours of training for substance abuse and controlled substances, and the state's direction to accept the 8 hours training in lieu of the training required in this rule until the rule is modified, the rule language needs to be corrected to edit the training content for those licensees who are required to obtain a DEA registration in subrule(1)(a) to include only utilizing the MAPS and State and federal laws regarding prescribing and dispensing controlled substances. The rule also needs to require others who do not get the DEA registration to meet all the subjects in the current rule and require the training for each cycle, not just a 1-time training. **Suggested Edits are highlighted in red.** Rule 35. (1) An individual who is applying for **or renewing** a controlled substance license ~~or who is licensed to prescribe or dispense controlled substances pursuant to~~**under** ~~section 7303 of the code, MCL 333.7303,~~ shall complete a ~~1-time~~ training in opioids and controlled substances awareness **before applying for the license or renewal. The training must meet** ~~that meets~~ the following standards: (a) Training content must cover ~~all~~**both** of the following topics: ~~(i) Use of opioids and other controlled substances.~~ ~~(ii) Integration of treatments.~~ ~~(iii) Alternative treatments for pain management.~~ ~~(iv) Counseling on the effects and risks associated with using opioids and other controlled substances.~~ ~~(v) The stigma of addiction.~~ ~~(vi)~~ Utilizing the MAPS. ~~(vii)~~ **(ii)** State and federal laws regarding prescribing and dispensing controlled substances. ~~(viii) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.~~ (b) Topics covered under subrule (1)(a) of this rule may be obtained from more than 1 program. (c) Acceptable providers or methods of training include ~~any of~~ the following: (i) Training offered by a nationally recognized or state-recognized health-related organization. (ii) Training offered by, or in conjunction with, a state or federal agency. (iii) Training offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the code, MCL 333.16101 to 333.18838. (iv) Training obtained in an educational program that has been approved by a board established under article 15 of the code, MCL 333.16101 to 333.18838, for initial licensure or registration, or by a college or university. (d) Acceptable modalities of training include ~~any of~~ the following: (i) Teleconference or webinar.

		(ii) Online presentation. (iii) Live presentation. (iv) Printed or electronic media. (2) A prescriber or dispenser ~~shall~~**may** ~~not~~ delegate, allow by a practice agreement, or order the prescribing~~,~~ or dispensing of a controlled substance as allowed by the code to an individual, other than a physician's assistant, only after the individual has complied with ~~subrules~~ **subrule** ~~(1) and~~ (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule. (3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, an individual shall provide an acceptable proof of completion of training, including ~~either~~**1** of the following: (a) A completion certificate issued by the training provider that includes the date, provider name, name of training, and individual's name. (b) A self-attestation by the individual that includes the date, provider name, name of training, and individual's name. (4) An individual who has been issued a controlled substance license ~~pursuant to~~**under** section 7303 of the code, MCL 333.7303, shall complete the controlled substance training required by subrule (1) of this rule as follows: (a) A licensee who is renewing ~~his or her~~**a** controlled substance license shall complete the controlled substance training by the end of the first renewal cycle that begins after January 4, 2019. (b) Other than a license renewal under subdivision (a) of this subrule, beginning September 1, 2019, the department shall not issue a controlled substance license until an applicant provides proof of having completed the controlled substance training. (5) ~~Beginning December 31, 2021,~~ **Except as exempted under subrule (6) of this rule, veterinarians and an** individual, other than a physician's assistant, who is a delegatee, or allowed by a practice agreement or an order to prescribe or dispense a controlled substance by a prescriber or dispenser as allowed by the code, shall complete ~~the~~ **a** controlled substance training ~~required by subrule (1) of this rule.~~ **The training must be taken one time during the current license cycle. The training must cover ~~that covers~~ all the following topics:** **(a) Use of opioids and other controlled substances.** **(b) Integration of treatments.** **(c) Alternative treatments for pain management.** **(d) Counseling on the effects and risks associated with using opioids and other controlled substances.** **(e) The stigma of addiction.** **(f) Utilizing the MAPS.** **(g) State and federal laws regarding prescribing and dispensing controlled substances.**

		(h) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances. (6) An individual who is licensed under section 7303 of the code, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals is exempt from this rule.
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

R 338.3135 Opioids and other controlled substances awareness training standards for prescribers and dispensers of controlled substances; requirements.

Rule 35. (1) An individual who is applying for **or renewing** a controlled substance license or ~~who~~ ~~is licensed to prescribe or dispense controlled substances pursuant to~~**under** ~~section 7303 of the code, MCL 333.7303,~~ shall complete a ~~1-time~~ training in opioids and controlled substances awareness ~~that meets~~ **before applying for the license or renewal. The training must meet** the following standards:

(a) Training content must cover ~~all~~ **both** of the following topics:

(i) ~~Use of opioids and other controlled substances.~~

~~(ii) Integration of treatments.~~

~~(iii) Alternative treatments for pain management.~~

~~(iv) Counseling on the effects and risks associated with using opioids and other controlled substances.~~

~~(v) The stigma of addiction.~~

~~(vi)~~ Utilizing the MAPS.

~~(vii)~~**(ii)** State and federal laws regarding prescribing and dispensing controlled substances.

~~(viii) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.~~

(b) Topics covered under ~~subrule (1)(a)~~ **subdivision (a)** of this ~~rule~~ **subrule** may be obtained from more than 1 program.

(c) Acceptable providers or methods of training include ~~any of~~ the following:

(i) Training offered by a nationally recognized or state-recognized health-related organization.

(ii) Training offered by, or in conjunction with, a state or federal agency.

(iii) Training offered by a continuing education program or activity that is accepted by a licensing board established under article 15 of the code, MCL 333.16101 to 333.18838.

(iv) Training obtained in an educational program that has been approved by a board established under article 15 of the code, MCL 333.16101 to 333.18838, for initial licensure or registration, or by a college or university.

(d) Acceptable modalities of training include ~~any of~~ the following:

(i) Teleconference or webinar.
(ii) Online presentation.
(iii) Live presentation.
(iv) Printed or electronic media.

(2) A prescriber or dispenser ~~shall not~~ **may** delegate, allow by a practice agreement, or order the prescribing~~,~~ or dispensing of a controlled substance as allowed by the code to an individual, other than a physician's assistant, only after the individual has complied with ~~subrules~~ **subrule** ~~(1) and~~ (5) of this rule. A physician's assistant is subject to subrules (1), (3), and (4) of this rule.

(3) The department may select and audit licensees and request documentation of proof of completion of training. A licensee shall maintain proof of completion of training for 3 renewal periods plus 1 additional year. If audited, ~~an~~ **the** individual shall provide an acceptable proof of completion of training, including ~~either~~**1** of the following:

(a) A completion certificate issued by the training provider that includes the date, **the** provider**'s** name, name of **the** training, and **the** individual's name.

(b) A self-attestation by the individual that includes the date, **the** provider**'s** name, name of **the** training, and **the** individual's name.

(4) An individual who has been issued a controlled substance license ~~pursuant to~~**under** section 7303 of the code, MCL 333.7303, shall complete the controlled substance training required by subrule (1) of this rule**,** as follows:

(a) A licensee who is renewing ~~his or her~~**a** controlled substance license shall complete the controlled substance training by the end of the first renewal cycle that begins after January 4, 2019.

(b) Other than a license renewal under subdivision (a) of this subrule, beginning September 1, 2019, the department shall not issue a controlled substance license until ~~an~~ **the** applicant provides proof of having completed the controlled substance training.

(5) ~~Beginning December 31, 2021,~~ **Except as expemted under subrule (6) of this rule, veterinarians and** an individual, other than a physician's assistant, who is a delegatee, or allowed by a practice agreement or an order to prescribe or dispense a controlled substance by a prescriber or dispenser as allowed by the code, shall complete ~~the~~ **a** controlled substance training ~~required by subrule (1) of this rule~~. **The training must be taken 1 time during the current license cycle and cover all of the following topics:**

(a) Use of opioids and other controlled substances.
(b) Integration of treatments.
(c) Alternative treatments for pain management.
(d) Counseling on the effects and risks associated with using opioids and other controlled substances.
(e) The stigma of addiction.
(f) Utilizing the MAPS.
(g) State and federal laws regarding prescribing and dispensing controlled substances.

(h) Security features for opioids and other controlled substances and prescriptions, and proper disposal requirements for opioids and other controlled substances.

(6) An individual who is licensed under section 7303 of the code, MCL 333.7303, to prescribe or dispense controlled substances only for research on animals**,** is exempt from this rule.

Board Response	

Rule 338.3141 Thefts and diversions.

Section Numbers	Commenter	Comment
Subrule 3	Baran	The DEA has set a time period when the registrant must file the 106 form which is different from the state requirement. "21 USC 1301.74 (c) ….The registrant must also file a complete and accurate DEA Form 106 with the Administration through the DEA Diversion Control Division secure network application within 45 calendar days after discovery of the theft or loss . . . ." **Suggested Change:** To be less confusing for licensees change the 15 days to 45 days.
Rules Committee Response	The committee agreed with the suggested change. Rule edits per the committee's suggestion are in red below.	

Board Response	

R 338.3141 Thefts and diversions.

Rule 41. (1) An applicant or licensee shall provide effective controls against theft and diversion of controlled substances.

(2) A licensee shall confirm that a person is licensed to possess a controlled substance before distributing the substance to the person.

(3) Within ~~15~~ **45** days ~~of~~ **after** completion of an investigation regarding a suspected theft or significant loss of a controlled substance, a licensee shall notify the department of the suspected theft or significant loss of a controlled substance and submit a copy of the DEA theft and loss report form 106, or equivalent document, to the department, whether or not the controlled substance is recovered or the responsible ~~person~~**individual** is identified and action is taken against ~~him or her~~**the responsible individual**, and whether or not it is also reported to the DEA.

(4) A licensee shall use all of the following criteria to determine if the loss in subrule (3) of this rule is significant:

(a) The quantity of the controlled substance lost in relation to the type of business.

(b) The specific controlled substance lost.

(c) Whether the loss of the controlled substance can be associated with access to the controlled substance by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substance.

(d) A pattern of loss over a specific time period, whether the loss appears to be random, and the results of efforts taken to resolve the loss.

(e) Whether the specific controlled substance is a likely candidate for diversion.

(f) Local trends and other indicators of the diversion potential of the missing controlled substance.

Rule 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.

Section Numbers	Commenter	Comment
Subrule 3	Baran	Controlled substance prescriptions must be kept on site. 21 CFR 1304.04(h) states paper prescriptions for Schedule II, III, IV and V controlled substances shall be maintained at the registered location in a separate prescription file. Deleting the on site would conflict with federal rules. **Suggested Change:** Leave on site in the rule.
Subrule 6	Baran	Schedule 2 order forms and controlled substance inventories are required by federal law to be stored at the pharmacy. Controlled substances in the automated dispensing system (ADS) belong to the pharmacy because the drugs are not considered dispensed until the ADS provides them, thus drugs in the ADS are counted as pharmacy inventory. Schedule 2 order forms (DEA 222 form) used to order the 2s for the ADS location belong to the pharmacy. The ADS at a different address than the pharmacy is not a pharmacy. See LARA's licensing guide for Controlled Substance Automated Device License. **Suggested Change:** Delete (6). The pharmacy is already required to maintain executed DEA 222 forms and controlled substance inventories. See Rule 338.3151(5) and 338.3153(1).
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.

Rule 53. **(1)** For 2 years, a licensee shall maintain in the pharmacy ~~responsible for the automated device,~~ for review by the department, an agency, or the board, all records for controlled substances, including invoices~~,~~ **and** acquisition records~~, and sales receipts,~~ as follows:

(a) A licensee may keep acquisition records, except for executed or voided DEA 222 order forms, in an electronic form at a central location with notice to the department.

(b) A licensee shall maintain invoices and other acquisition records of all controlled substances listed in schedules 1 and 2 in a separate file from invoices and other acquisition records of controlled substances listed in schedules 3, 4, and 5. The information must be readily retrievable from the ordinary acquisition records maintained by the dispenser.

~~(c) A licensee shall retain sales receipts for 90 days in electronic or paper form.~~

(~~d~~**c**) A licensee shall initial or electronically initial the invoice and indicate the date that the controlled substances are received.

(2) A licensee shall maintain in the pharmacy for review by the department, an agency, or the board, patient sales receipts and dispensing records as follows:

(a) A licensee shall retain patient sales receipts for 90 days in electronic or paper form.

~~(e)~~**(b)** A licensee shall keep a record, which may be electronic, of all controlled substances dispensed by ~~him or her~~**the licensee**.

~~(f)~~**(c)** A licensee that prescribes controlled substances shall keep a record separate from the patient chart ~~which~~**that** contains all of the following information for controlled substances dispensed or administered by the prescriber:

(i) Name of the patient.

(ii) Name and strength of the controlled substance.

(iii) Quantity of the controlled substance.

(iv) Date the controlled substance was dispensed or administered.

(v) Name of the individual who dispensed or administered the controlled substance.

~~(g)~~**(d)** Except in medical institutions, a licensee shall sequentially number and maintain in chronological order the patients' original prescriptions as follows:

(i) A licensee shall maintain a separate file for dispensed substances listed in schedule 2.

(ii) A licensee shall maintain a separate file for dispensed substances listed in schedules 3, 4, and 5.

~~(h)~~**(3)** ~~The~~**A** licensee shall keep the original prescription record on site for 5 years ~~from~~**after** the last date of dispensing. However, ~~after~~ 2 years ~~from~~**after** the last date of dispensing, ~~if an electronic duplicate is made of the original paper prescription, which becomes the original prescription, the original prescription may be destroyed~~ **a licensee may make an electronic duplicate of the original paper prescription, which becomes the original prescription**.

~~(i)~~**(4)** A licensee shall maintain records of controlled substances distributed to another licensee~~, which shall~~ **that must** include all of the following information and be maintained in the appropriate file described in ~~subdivision~~ **subrule (1)**(b) of this rule or in a separate record that is available for inspection:

(~~i~~**a**) Name, address, and DEA number of receiver.

(~~ii~~**b**) Name, address, and DEA number of supplier.

(~~iii~~**c**) Name and quantity of the controlled substances distributed.

(~~iv~~**d**) Date the controlled substances were distributed.

(j5) A DEA 222 order form must be used for schedule 2 drugs.

~~(k) Except for controlled substance prescriptions pursuant to subdivision (h) of this rule, a licensee shall maintain controlled substances records for 2 years.~~

~~(6) A pharmacy that holds an additional license for an automated dispensing system that dispenses controlled substances shall store inventories and schedule 2 order forms at the licensed location of the automated device.~~

Board Response	

Rule 338.3161 Controlled substance prescriptions.

Section Numbers	Commenter	Comment
(1)(b) and (6)	Chludzinski	R 338.3161(1)(b) does not require the prescriber's professional designation to be on a prescription, but R 338.3161(6) states that the professional designation must be stored electronically. If the prescriber isn't required to supply a professional designation on a prescription, how will a pharmacy identify and store it?
(6)	Baran	Stored electronically is vague. It could be stored in a separate computer or in a separate word file from the pharmacy's automated data processing system. **Suggested Change:** The professional designation for the prescribing practitioner must be stored electronically in the pharmacy's automated data processing system.
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

R 338.3161 Controlled substance prescriptions.

Rule 61. (1) A prescription that is issued for a controlled substance must be dated and signed by the prescriber, when issued, and contain all of the following information:

(a) The full name and address of the patient for whom the substance is being prescribed.

(b) The prescriber's DEA registration number, preprinted, stamped, typed, or manually printed name, address, **and** telephone number or pager number, and professional designation~~.~~ **that is either written on the prescription or stored in the pharmacy's automated data processing system.**

(c) The drug name, strength, and dosage form.

(d) The quantity prescribed. For a paper prescription received in writing, the prescription must contain the quantity in both written and numerical terms. A paper prescription **complies if it** ~~must contain~~**contains** preprinted numbers representative of the quantity next to a box or line that the prescriber may check.

(e) The directions for use.

(f) If the prescription is for an animal, ~~then~~ the species of the animal and the full name and address of the owner.

(2) A written prescription for a controlled substance **listed** in schedules 2 to 5 ~~shall~~**must** be written legibly with ink or an indelible pencil or prepared using a printer and signed by the prescriber.

(3) An agent of the prescriber may prepare a prescription for the signature of the prescriber, ~~but,~~ **however,** ~~pursuant to~~**under** ~~the code~~**sections 16106 and 17744 of the code, MCL 333.16106 and 333.17744**, the prescriber is liable if the prescription does not conform to these rules. A pharmacist who dispenses a controlled substance ~~pursuant to~~**under** a prescription not prepared in the form required by these rules is liable ~~pursuant to~~**under** the code.

(4) If the controlled substance prescription or order in a medical institution is issued ~~pursuant to~~**under** delegation, ~~then~~ the printed name of the delegatee, the licensure designation, the delegating prescriber, and the signature of the delegatee ~~shall~~**must** be on the written prescription. In medical facilities, orders must contain the signatures of the delegatee and the printed name of the delegating prescriber.

(5) A prescriber shall not issue a prescription to obtain a stock of a controlled substance for the purpose of dispensing or administering the substance to patients.

~~**(6) The professional designation for the prescribing practitioner must be stored electronically.**~~

Board Response	

Rule 338.3162a Electronic transmission of prescription; waiver of electronic transmission.

Section Numbers	Commenter	Comment
	Baran	Section 333.17754 no longer applies. Rule revised to meet 333.17754a. **Suggested Change:** R 338.3162a Electronic transmission of prescription; waiver of electronic transmission. Rule 62a. (1) ~~Until the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted~~

		~~prescription, if all of the following conditions are satisfied:~~ **Effective on January 1, 2023 prescribers shall, unless an exception under section 17754a of the code, MCL 333.17754a, applies, electronically transmit a prescription and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:** (a) The prescription is transmitted to the pharmacy of the patient's choice and occurs only at the option of the patient. (b) The electronically transmitted prescription includes all of the following information: (i) The name and address of the prescriber. (ii) An electronic signature or other board-approved means of ensuring prescription validity. (iii) The prescriber's telephone number for verbal confirmation of the order. (iv) The time and date of the electronic transmission. (v) The name of the pharmacy intended to receive the electronic transmission. (vi) Unless otherwise authorized under section 17754(1)(b) of the code, MCL 333.17754, the full name of the patient for whom the prescription is issued. (vii) All other information that must be contained in a controlled substance prescription under R 338.3161. (c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription. (d) All requirements in section 17754**a** of the code, MCL 333.17754**a**, are met. (2) An electronically transmitted prescription that meets the requirements of subrule (1) of this rule is the original prescription. (3) ~~Effective **on** the enforcement date established by the federal Centers for Medicare and Medicaid Services**CMS** for the Medicare electronic transmission requirement, prescribers shall, unless an exception under section 17754a of the Code, **code**, MCL 333.17754a, applies, electronically transmit a prescription for a controlled substance consistent with both of the following requirements:~~ ~~(a) All the requirements in section 17754a of the code, MCL 333.17754a, are met.~~ ~~(b) All the requirements in R 338.3161 are met.~~ ~~(4)~~ A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and satisfy either of the following requirements:

		(a) The prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the ~~federal Centers for Medicare and Medicaid Services~~**CMS**. (b) The prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code, MCL 333.17754a, and the prescriber meets 1 of the following: (i) ~~The prescription is dispensed by a dispensing prescriber.~~ The prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber. (ii) The prescriber demonstrates by attesting to exceptional circumstances, including, but not limited to, the following: (A) Prescribing fewer than 100 controlled substances prescriptions per year or the number of controlled substances prescriptions used in the ~~Federal Centers for Medicare and Medicaid Services~~**CMS** waiver for electronic transmission of prescriptions for controlled substances, whichever is more. (B) **The prescriber has or intends within the next 12 months to no longer regularly practice their licensed profession for financial gain or as a means of livelihood**~~Intention to cease practice within the next twelve months~~. (C) Limited practice due to an illness or other unforeseen event. ~~(iv)~~**(iii)** The prescriber issues prescriptions from a ~~non-profit charitable~~ **not-for-profit** medical clinic **that provides free or low-cost services to the public**. ~~(5)~~ (4)A waiver is valid for 2 years and ~~is applicable~~**applies** to the specific circumstances included in the application. A waiver may be renewed by application to the department.
Rules Committee Response	The committee agreed with the suggested changes. Rule edits per the committee's suggestion are in red below.	

R 338.3162a Electronic transmission of prescription; waiver of electronic transmission.

Rule 62a. (1) ~~Until the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:~~ **Prescribers shall, unless an exception under section 17754a of the code, MCL 333.17754a, applies, electronically transmit a prescription and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:**

(a) The prescription is transmitted to the pharmacy of the patient's choice and occurs only at the option of the patient.

(b) The electronically transmitted prescription includes all of the following information:

(i) The name and address of the prescriber.

(ii) An electronic signature or other board-approved means of ensuring prescription validity.

(iii) The prescriber's telephone number for verbal confirmation of the order.

(iv) The time and date of the electronic transmission.

(v) The name of the pharmacy intended to receive the electronic transmission.

(vi) Unless otherwise authorized under section 17754(1)(b) of the code, MCL 333.17754, the full name of the patient for whom the prescription is issued.

(vii) All other information that must be contained in a prescription under R 338.3161.

(c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.

(d) All requirements in section 17754 of the code, MCL 333.17754, are met.

(2) An electronically transmitted prescription that meets the requirements of subrule (1) of this rule is the original prescription.

(3) ~~Effective **on** the enforcement date established by the federal Centers for Medicare and Medicaid Services~~**CMS** ~~for the Medicare electronic transmission requirement, prescribers shall, unless an exception under section 17754a of the Code, **code**, MCL 333.17754a, applies, electronically transmit a prescription for a controlled substance consistent with both of the following requirements:~~

~~(a) All the requirements in section 17754a of the code, MCL 333.17754a, are met.~~

~~(b) All the requirements in R 338.3161 are met.~~

~~(4)~~ A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and satisfy either of the following requirements:

(a) The prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the ~~federal Centers for Medicare and Medicaid Services~~**CMS**.

(b) The prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code, MCL 333.17754a, and the prescriber meets 1 of the following:

(i) ~~The prescription is dispensed by a dispensing prescriber.~~

~~(ii)~~ The prescriber demonstrates economic hardship or technological limitations that are not within the control of the prescriber.

~~(iii)~~**(ii)** The prescriber demonstrates by attesting to exceptional circumstances, including, but not limited to, the following:

(A) Prescribing fewer than 100 controlled substances prescriptions per year or the number of controlled substances prescriptions used in the ~~Federal Centers for Medicare and Medicaid Services~~**CMS** waiver for electronic transmission of prescriptions for controlled substances, whichever is more.

(B) **The prescriber has or intends within the next 12 months to no longer regularly practice their licensed profession for financial gain or as a means of livelihood**~~Intention to cease practice within the next twelve months~~.

(C) Limited practice due to an illness or other unforeseen event.

~~(iv)~~**(iii)** The prescriber issues prescriptions from a ~~non-profit charitable~~ **not-for-profit** medical clinic **that provides free or low-cost services to the public**.

~~(5)~~**(4)** A waiver is valid for 2 years and ~~is applicable~~**applies** to the specific circumstances included in the application. A waiver may be renewed by application to the department.

Board Response	

Rule 338.3162b Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances.

Section Numbers	Commenter	Comment
Subrule (1)(a)(i)	Baran	To add tribal government identification **Suggested Change:** (a) The patient identifier identification number. ~~For purposes of~~**As used in** this subdivision, all of the following apply: (i) An identification number, as specified in R 338.3102~~(1)~~(~~f~~**h**)(iv)(A) to (~~C~~**E**), is not required for patients under the age of 16.
Rules Committee Response	The committee agreed with the suggested change. Rule edits per the committee's suggestion are in red below.	

R 338.3162b Electronic system for monitoring schedules 2, 3, 4, and 5 controlled substances.

Rule 62b. (1) Except as otherwise exempt under section 7333a of the code, MCL 333.7333a, a pharmacist, dispensing prescriber, ~~and~~ **or** veterinarian licensed under ~~Part~~ **part** 177 of the code, MCL 333.17701 to 333.17780, who dispenses a prescription drug that is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by ~~the~~ **this** state that dispenses in this state or dispenses to an address in this state a controlled substance listed in schedules 2 to 5**,** shall report to the department or the department's contractor by means of an electronic data transmittal process**,** the following information for each prescription of a scheduled 2 to 5 controlled substance that has been dispensed:

(a) The patient identifier identification number. ~~For purposes of~~**As used in** this subdivision, all of the following apply:

(i) An identification number, as specified in R 338.3102~~(1)(f)(iv)~~**(h)**(A) to (~~C~~**E**), is not required for patients under the age of 16.

(ii) If the patient is under 16 years of age, zeroes must be entered as the identification number.

(iii) If the medication being dispensed is for an animal, the patient identification number applies to the animal's owner, the client, that meets the requirements of R ~~338.3102(1)(f)(iv).~~ **338.3102(h)(iv).** If the animal's owner cannot be identified, zeroes must be entered as the identification number.

(b) The patient's name; client's name, including first name, middle name, or middle initial, if available; and last name.

(c) The patient's or client's address, including street, city, state, and zip code.

(d) The patient's or client's phone number.

(e) The patient's or client's gender.

(f) The patient's or client's date of birth.

(g) The species code, as specified by ASAP.

(h) The metric quantity of the controlled substance dispensed.

(i) The NDC of the controlled substance dispensed.

(j) The date **the prescription is issued.** ~~of issue of the prescription.~~

(k) The date ~~of dispensing~~**the prescription is filled**.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

(n) The estimated days of supply of the controlled substance dispensed.

(o) The prescription number assigned by the dispenser.

(p) The prescription transmission form code, as specified by ASAP, that indicates how the pharmacy received the prescription.

(q) The prescription payment type. Cash discount cards are considered cash transactions.

(r) The electronic prescription reference number, if applicable.

(s) The patient's or client's location code when receiving ~~pharmacy~~ **the dispensed controlled substance**, as specified by ASAP.

(t) The DEA registration number of the prescriber and the dispensing pharmacy.

(2) A pharmacist, dispensing prescriber, or veterinarian may presume that the patient identification information provided by a patient, ~~or~~ a patient's representative, or veterinarian's client is correct.

(3) As used in this rule, R 338.3162c, and R 338.3162d, ~~the term~~ "dispense" or "dispensing" means the preparation, compounding, packaging, or labeling of a controlled substance along with delivery of the controlled substance ~~pursuant to~~**under** a prescription or other authorization issued by a prescriber, and does not include the acts of prescribing a controlled substance or administering a controlled substance directly to a patient.

(4) As used in this rule, ~~the term~~ "patient" ~~refers to~~ **means** an individual, not an animal.

Board Response	

Rule 338.3162c Format for electronic transmission of data to electronic system for monitoring; waiver.

Section Numbers	Commenter	Comment
Subrule (2)	Baran	To bring it current with ASAP standard. **Suggested Change:** (2) The data must be transmitted in the format established by the ASAP ~~4.1~~ 5 Standard for Prescription Drug Monitoring Programs.
Rules Committee Response	The committee agreed with the suggested change. Rule edits per the committee's suggestion are in red below.	

R 338.3162c Format for electronic transmission of data to electronic system for monitoring; waiver.

Rule 62c. (1) A pharmacist, dispensing prescriber, or veterinarian who dispenses a prescription drug that is a controlled substance listed in schedules 2 to 5 shall transmit the data, as specified under R 338.3162b**,** by electronic media or other means as approved by the department or the department's contractor.

(2) The data must be transmitted in the format established by the ASAP ~~4.1~~5 Standard for Prescription Drug Monitoring Programs.

(3) A pharmacist, dispensing prescriber, or veterinarian who dispenses controlled substances and ~~who~~ does not have an automated record-keeping system capable of producing an electronic report in the format established by subrule (2) of this rule may request a waiver from electronic reporting. The request ~~shall~~**must** be made in writing to the department.

(4) A pharmacist, dispensing prescriber, or veterinarian may be granted a waiver, if ~~he or she~~**the pharmacist, dispensing prescriber, or veterinarian** demonstrates an inability to report as required by R 338.3162b and ~~he or she~~ agrees in writing to report the data to the department or the department's contractor by submitting a completed MAPS claim form ~~, as defined in R 338.3102(1)(c),~~ or transmitting data via an internet web portal that is provided by the department or the department's contractor for this purpose.

Board Response	

Rule 338.3165 Emergency dispensing of schedule 2 substances; written prescriptions.

Section Numbers	Commenter	Comment
Subrule (1)	Baran	DEA under 1306.11(d) only allows a written prescription for an oral emergency prescription not an electronic

		prescription. **Suggested Change:** (a) The prescriber shall deliver to the dispensing pharmacist a written prescription **postmarked within 7 days after the date the prescription was dispensed,** ~~or electronically transmit the prescription~~ ~~pursuant to~~**under** R 338.3162a. (c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **the pharmacy** ~~either~~ a written prescription ~~or a prescription transmitted electronically~~.
Rules Committee Response	The committee elected not to make the suggested change as the code allows both options.	

R 338.3165 Emergency dispensing of schedule 2 substances; written prescriptions.

Rule 65. (1) ~~Within 7 days after~~**After** authorizing an emergency oral prescription of a controlled substance listed in schedule 2, the prescriber shall comply with all of the following **within 7 days**:

(a) The prescriber shall deliver to the dispensing pharmacist a written prescription **postmarked within 7 days after the date the prescription was dispensed,** or electronically transmit the prescription ~~pursuant to~~**under** R 338.3162a.

(b) The prescriber shall include on the prescription both "Authorization for Emergency Dispensing" and the date of the oral order.

(2) A pharmacist that has dispensed a prescription on an emergency oral prescription shall comply with all of the following:

(a) The dispensing pharmacist shall reduce the oral prescription to writing.

(b) ~~Upon receipt of the prescription, the~~ **After the** dispensing pharmacist **receives the prescription the pharmacist** shall attach the prescription to the oral order ~~which~~**that** was earlier reduced to writing.

(c) The pharmacy shall notify the department if the prescriber fails to deliver to ~~him or her~~ **the pharmacy** either a written prescription or a prescription transmitted electronically.

(3) The failure of the pharmacy to notify the department if the prescriber fails to deliver a prescription ~~pursuant to~~**under** subrule (1) of this rule voids the authority conferred by this rule.

Board Response	

Rule 338.3183 Distribution to suppliers.

Section Numbers	Commenter	Comment
Entire Rule	Baran	The rule is confusing. If the intent of this rule is to allow a licensee to return controlled substances from whom they obtained the drug lawfully it is already allowed under R 338.3153.

		Suggested Change: Delete entire rule.
Rules Committee Response	The committee elected not to make the suggested change as R 338.3153 does not adequately handle the content of this rule.	

R 338.3183 Distribution to suppliers.

Rule 83. (1) A**n** ~~person~~ **individual** who is lawfully in possession of a controlled substance that is listed in ~~any~~**a** schedule may ~~distribute~~**return** the substance to the ~~person~~ **individual who gave the person** ~~from whom he or she obtained~~ the substance or to the manufacturer of the substance without obtaining a license to distribute. The ~~person~~ **individual** who distributes the substance shall maintain a written record that contains all of the following information:

(a) The date of the distribution.

(b) The name, form, and quantity of the substance.

(c) The name, address, and license number, ~~if any,~~ of the ~~person~~ **individual** who ~~makes the distribution~~**distributes the substance**.

(d) The name, address, and license number, if known, of the supplier or manufacturer.

(2) In the case of a controlled substance listed in schedules 1 or 2, an order form must be used and maintained as the written record of the distribution.

Board Response	