MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
SEPTEMBER 14, 2021

The Michigan Board of Pharmacy Rules Committee Work Group met on September 14, 2021. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman called the meeting to order at 8:01 a.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph.
Charles Mollien, PharmD, JD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.

Members Absent: None

Staff Present: Andria Ditschman, Senior Policy Analyst, Boards and Committees Section
Stephanie Wysack, Board Support, Boards and Committees Section

Public Present: Deeb Eid - CVS Pharmacy
Stacey Hettiger – Michigan State Medical Society
Kathleen Westfall – Legal Counsel, Michigan State Medical Society

RULES DISCUSSION

Ditschman explained that she would walk the Rules Committee through the comments received from the public hearing that was held on the Controlled Substance draft rules on September 9, 2021. She stated that the Rules Committee's recommendations would be added to the Public Comment Summary and presented to the Board at the meeting on October 1, 2021.

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

General:

Mankowski comment: Ditschman stated that several citations were missed at the beginning of the draft.

The Rules Committee agreed with the comment and the addition of the listed citations.

Lambert comment: Ditschman stated that Ms. Lambert's comment was regarding doctors not prescribing controlled substances for pain because of all of the limitations on prescribing. Ms. Lambert's complaint is that some people, like her, need these medications for pain. Ditschman stated that as Ms. Lambert's comments do not pertain to a rule, but rather relate to the Public Health Code provisions, she was referred to talk to her state representative regarding her concerns.

R 338.3132 Controlled substance license.

Section (8)(g): Eid explained his comment, stating that the DEA does not require a separate license for an emergency kit for use in emergency situations.

Boutros stated that the use/inventory is already documented by the pharmacy.

Mollien stated that the storage is already covered under the DEA registration but asked if the concern was that the emergency kit could be stored in a location that was not the pharmacy.

Discussion was held.

Mollien stated that this topic needed further research and should be discussed in a future rule set.

The Rules Committee agreed to hold for a future rule set and rejected the comment.

Sections (3) and (8): Ditschman stated that the comment requested to reorganize the activities requiring a separate controlled substance license in one provision and exceptions to the requirements in another provision. Ditschman confirmed with Hettiger that no activities or exceptions were deleted, they were just reorganized.

Hettiger confirmed that Ditschman's statement was correct.

The Rules Committee agreed with the comment.

R 338.3137 Waiver of license requirement.

Ditschman stated that the Department required a Drug Treatment Prescriber license. It is believed that this license was required due to the Department's interpretation of the "good faith" wording in the Code. This proposed rule will waive the license requirement that the Department established under the Code.

Novak comment: Ditschman stated that the comment indicated that the Michigan State Medical Society (MSMS) did not believe that a waiver rule was needed as the license required by the Department was not authorized by the Code.

Hettiger explained that since the language in R 338.3132 had been removed, leaving the waiver rule in R 338.3137 caused confusion. The requirement is also further covered under R 338.3163.

MHA comment: Ditschman stated that this comment indicated if the waiver language were to stay, a reference to the Drug Treatment Prescriber license needed to be added for clarity.

Taylor stated that the language should stay in order to provide clarity/comfort to the prescribers.

Westfall stated that referencing a license that is not in the statute caused confusion and that maybe an exception to "good faith" could be included.

Discussion was held.

Mollien stated that a rule stating that the Drug Treatment Prescriber license is gone would suffice.

The Rules Committee agreed with the language suggested by Mollien.

R 338.3151 Inventories.

Section (5): Ditschman read the comment.

The Rules Committee agreed with the suggested change.

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

Section (a): Ditschman read the comment.

The Rules Committee agreed with the suggested change.

Section (b): Baran explained that the rule is not clear that it applies to schedule 3, 4, and 5 invoices and acquisition records.

Mollien stated that the comment was covered under sections (a) and existing section (b).

The Rules Committee rejected the comment as the information was addressed in the rule.

Section (c): Ditschman read the comment.

Sleiman stated that electronic should be included with the changes that occur in technology.

Mollien stated that it could be eliminated as MCL 333.17757 covers that with the definition of a receipt.

The Rules Committee agreed with the comment to add to the rule that a sales receipt may be kept electronically or in paper form. The Rules Committee did not agree to define sales receipt as the definition of receipt is included in the code.

R 338.3154 Medication records in medical institutions.

Section (5)(h)(vi): Ditschman read the comment.

Mollien stated that he did not see where the rule required the license number to be entered, as the rule only required that it be kept and readily retrievable.

Taylor stated that just identification was needed.

Discussion was held.

The Rules Committee agreed with the comment to remove “name and license number” and will replace it with “identification.”

Section (5)(f)(xix)(B): Eid explained his comment, stating it was different than the previous rule and emergency kits under R 338.3132. He stated that striking out this section would align the rule with the DEA requirements.

Mollien stated that this rule covered the review of the prescription or medication order by the pharmacist for safety reasons, after the physician dispenses, not the writing of the prescription.

Discussion was held.

The Rules Committee rejected the comment as it was not inconsistent with the DEA regulations as it had to do with the review of the prescription, not the issuance of the prescription, and the rule was needed for safety reasons.

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

Ditschman stated that many comments were received regarding the use of October 1, 2021, as the effective date that is listed in the code, and January 1, 2022, which is the effective date in the proposed Pharmacy – General Rules. Ditschman stated that the code required that the mandate be effective October 1, 2021, however, it also stated that the Department will delay the implementation of the mandate to the date established by the Federal Centers for Medicare and Medicaid Services for electronic transmission of prescription for controlled substances.

Discussion was held about what dates to use. It was decided that for clarity and to avoid confusion, and to deal with the situation where CMS further delays enforcement of the mandate, the Rules Committee would recommend that all dates be deleted and instead state that the mandate would be enforced on the date the mandate is enforced by CMS.

Eid comment: Eid clarified that the comment was just an FYI, not a suggestion for a change.

Cargill and Young comments: The Rules Committee will address hospice in the next rules set.

Section (4): Carlson and Novak comments.

Ditschman stated that these comments ask for clarification on exceptions and a waiver, providing two routes.

Mollien stated he agreed that listing them separately would clarify.

ADJOURNMENT

Ditschman stated that we would need to pick up the Public Comment Summary at the next Rules Committee Work Group meeting on September 24, 2021.

Ditschman adjourned the meeting at 10:00 a.m.

Prepared by:
Stephanie Wysack, Board Support — September 20, 2021
Bureau of Professional Licensing

Pharmacy – Controlled Substances - ORR 2020-082 LR
Public Comment Summary
Rules Committee Recommendations to September 9, 2021 Public Comments

Testimony/Comments Received:

Rose Baran, PharmD
Barry Cargill, President & CEO, Michigan HomeCare and Hospice Association (MHHA)
Adam Carlson, Vice President, Advocacy, Michigan Health & Hospital Association (MHA)
Deeb Eid, Advisor, Pharmacy Regulatory Affairs, CVS Health
Timothy Gammons, President, Michigan Society of Addiction Medicine (MISAM)
Kolinda Lambert
Alicia Mankowski, Pharmacy Compliance Specialist, Meijer
Julie Novak, Chief Executive Officer, Michigan State Medical Society (MSMS)
Brian Sapita, Director of Government Affairs, Michigan Pharmacists Association (MPA)
Lori Smoker Young, Hospice Care of Southwest Michigan

General

Rule Numbers	Commenter	Comment
Authority Paragraph	Mankowski	The following citations should be added to the authority paragraph, as they also authorize these rules: MCL 333.16141, MCL 333.16201, MCL 333.16204, MCL 333.16204e, MCL 333.16205, MCL 333.16215, MCL 333.16287, MCL 333.17707, MCL 333.17721, MCL 333.17739, MCL 333.17742a, MCL 333.17742b, MCL 333.17748e, MCL 333.17754a, MCL 333.17775.

	Lambert	Objected to controlled substances being limited to a certain amount as doctors are afraid to prescribe medicines.
Rules Committee Response	Mankowski - The Rules Committee agrees that the suggested citations be included in the rules. Lambert - The Rules Committee	

Rule 338.3132 Controlled substance license.

Rule Numbers	Commenter	Comment
Section (8)(g)	Eid	Add the following to the end of (g): **This requirement shall not apply to emergency kits (automated or non) being used for emergency situations.** Rationale: In 2016, the American Society of Consultant pharmacist posed the question to the DEA about whether emergency kits (ekits) needed to obtain separate registrations based on 21 CFR 1301.27 and policy statement 70 FR24128 from 4/9/80. The DEA advised that ekits whether they are electronic or not remain subject to the previous policy set forth and do not require separate registration provided they satisfy the requirements of the policy. The DEA also stresses in their letter the ekit must be in use for emergency purposes only to be an exception to the registration requirement. We are recommending adding in an exception for emergency kits to ensure alignment with DEA/federal guidance and to avoid extra regulatory burden. References: • https://cdn.ymaws.com/ascp.site-ym.com/resource/collection/6F78F67D-C454-4D89-BCE1-F0C7A17755B3/November_30_DEA_Response_Letter.pdf
Sections (3) and (8)	Novak	Subrules (3) and (8) appear to be both duplicative and contradictory. For clarity purposes, MSMS suggests that activities requiring a separate controlled substance licenses be included in subrule (3), while exceptions to that requirement be addressed in subrule (8) and (9). MSMS believes that subrules (3) and (8) should be revised to read as follows:

		(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 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 filed and approved by the FDA and the DEA pursuant to 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 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 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 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 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 section 17760 of the code, MCL 333.17760, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as 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. (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 licensed pharmacy in this state.
Rules Committee Response	Section (8)(g) Eid - The Rules Committee declines to add the comment "this requirement shall not apply to emergency kits (automated or non) being used for emergency situations" as the exception to the licensing requirement is not in the best interest of the public. Section (3) and (8) Novak – The Rules Committee agrees with the comment to reorganize (3) and (8) for clarity.	

R 338.3132 ~~Activities requiring separate licenses~~ **Controlled substance license**.

Rule 32. (1) ~~The following activities are deemed to be independent of each other, shall be conducted under separate licenses, and shall comply with all of the requirements and duties prescribed by law for persons who are licensed to engage in such coincidental activities:~~ **A person who 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 fee.**

(2) In addition to meeting the requirements of section 7303 of the code, MCL 333.7303, an applicant's license shall be verified by the licensing agency of any state of the United States in which 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 for a prescriber or practitioner in subrule (8)(b)(ii) of this rule, a separate license is required for each principal place of business or professional practice where the applicant stores, manufactures, distributes, prescribes, or dispenses controlled substances.

(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 the article 15 license 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 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 is filed and approved by the FDA and the Federal Drug Enforcement Administration (DEA) pursuant to the provisions of 21 CFR 1301.18.

(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 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 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 is filed and approved by the FDA and the DEA pursuant to the provisions of 21 CFR 1301.18.

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

(8) The following activities require a separate controlled substance license.

(a) Manufacturing and distributing a controlled substance **in schedules 2-5**. ~~A person~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity** ~~who~~ **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**.

(b) Dispensing a controlled substance listed in schedules 2 to 5. A ~~physician~~ **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**.

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

(ii) 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 physical location of the business or professional practice if the prescriber or practitioner only prescribes at each physical location of the business or professional practice.

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

~~(A)~~ **(i)** Manufacture the **specific** substances as set forth in the research protocol that is filed and approved by the ~~federal food and drug administration~~ **FDA** and the ~~drug enforcement administration~~ ~~(~~DEA~~)~~ pursuant to the provisions of 21 ~~C.F.R.~~§**CFR** 1301.18 and submitted **to the department** with the application for licensure. ~~The Code of Federal Regulations, Title 21, Food and Drugs, part 1301, containing §1301.18 is available free of charge via the Internet at web site http://www.gpoaccess.gov. Printed copies may be purchased by mail order from the United States Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954, USA, by calling toll free at 1-866-512-1800, or via the Internet at web site http://bookstore.gpo.gov at a cost of $24.00 as of the time of adoption of these amendments. Printed copies of 21 C.F.R. §1301.18 also are available for inspection and for distribution to the public at cost at the, Department of Community Health, Bureau of Health Professions, Ottawa Building - First Floor, 611 West Ottawa, , Lansing, MI 48909.~~

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

~~(ii) A licensed physician who is authorized to conduct research with schedule 1 substances under federal law may conduct research with those substances, upon furnishing the administrator with evidence of that federal authorization. A separate license is not required for the research activity.~~

(d) Conducting research with a controlled substance listed in schedules 2 to 5. ~~A person~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity** who is licensed ~~or authorized~~ **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~~ **Conduct** chemical analysis with the **specific** substances listed in those schedules~~,~~**.**

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

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

(iv) ~~and conduct~~ **Conduct** instructional activities with the **specific** substances.

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

~~(f) Prescribing, dispensing, or administering a controlled substance to a drug-dependent person in a drug treatment and rehabilitation program.~~

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

(g) A pharmacy stocking patient medication in an automated device located at an affiliated hospital location pursuant to section 17760 of the code, MCL 333.17760, or a hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as 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.

~~(2) A~~ **a** ~~a~~separate license is required for each principal place of business or professional practice. A principal place of business or a professional practice is the physical location where controlled substances are manufactured, grown, cultivated, processed, or by other means produced or prepared, distributed, stored, or dispensed by a licensee.

~~(3) If a principal place of business or professional practice consists of multiple locations, then each location shall obtain a separate controlled substance license if controlled substances are received, stored, administered, or dispensed at that location.~~

~~(4) A prescriber or practitioner who holds a controlled substance license to prescribe, administer, or dispense controlled substances at a principal place of business or professional practice consisting of multiple locations shall not be required to obtain a separate controlled substance license for each physical location of the principal place of business or professional practice if the prescriber or practitioner only prescribes at the location .~~

~~(5) A pharmacist who holds a controlled substance license may dispense from any licensed pharmacy.~~

~~(6) A separate controlled substances license is required, as provided in R 338.3154(4), when controlled substances are stored in an automated device and the automated device is not located at the same address as the pharmacy responsible for the device.~~

Rule 338.3137 Waiver of license requirement.

Rule Numbers	Commenter	Comment
Rule 37		The MHA is supportive of the proposed change in R 338.3137, Rule 37 where the Bureau is waiving the Drug Treatment Program Prescriber License that is currently required. This is removing a barrier to patient access to care and sustained recovery since primary care physicians will be able to assist in prescribing buprenorphine for substance use treatment without getting and maintaining an additional license. Prescribers are already required to have a Michigan Controlled Substance License to prescribe controlled substances pursuant to statute and rule. To help provide clarity, we recommend referencing the Drug Treatment Program Prescriber License so providers understand which license is being discussed.
Rule 37	Novak	MSMS strongly supports the Department's proposed elimination of the requirement for a separate controlled substance license for prescribing, dispensing, or administering a controlled substance to a drug dependent person in a drug treatment and rehabilitation program presently addressed in Mich Admin Code R. 333.3132(1)(f), also known as the Drug Treatment Program Prescriber license requirement. The Michigan Drug Treatment Program Prescriber license is neither acknowledged nor authorized by the Michigan Public Health Code. MSMS believes this elimination is consistent with the state's policy goals of ensuring greater access to treatment for persons diagnosed with opioid use disorder. For these reasons and as further discussed below, MSMS believes that proposed Rule 37 should be eliminated in its entirety. MSMS believes that the Department should eliminate proposed Rule 37. As stated above, MSMS

		strongly supports the elimination of the Drug Treatment Program Prescriber license requirement for prescribers who are authorized under federal law to prescribe, dispense or administer controlled substances to individuals with substance use disorder. With the proposed elimination of the requirement to have a separate controlled substance license for prescribing, dispensing, or administering a controlled substance to a drug dependent person in a drug treatment and rehabilitation program under Rule 32, proposed Rule 37 is both moot and confusing. It is also duplicative of proposed Rule 63, which requires compliance with federal law to provide treatment to a "drug-dependent individual."
Rules Committee Response	The Rules Committee agrees with the comments to provide clarity in the rule by stating that the Drug Treatment Program Prescriber license is eliminated not waived.	

R 338.3137 ~~Waiver of~~ **Eliminate drug treatment program prescriber** license requirement.

Rule 37. ~~(1)~~ The **drug treatment program prescriber license is eliminated.** ~~requirement of licensure is waived for the following persons in the circumstances described in this rule: **a prescriber, possessing a license issued under section 7303 of the code, MCL 333.7303, who meets both of the following:**~~

~~**(a) A prescriber, who in the course of his or her professional practice, prescribes, dispenses, or administers a controlled substance listed in schedules 2 to 5 to a drug-dependent person for the purpose of maintenance or detoxification treatment.**~~

~~**(b) A prescriber who is registered with the DEA to provide maintenance or detoxification treatment and who complies with federal law.**~~

~~(a) An officer or employee of the drug enforcement administration while engaged in the course of official duties.~~

~~(b) An officer of the United States customs service while engaged in the course of official duties.~~

~~(c) An officer or employee of the United States food and drug administration while engaged in the course of official duties.~~

~~(d) A federal officer who is lawfully engaged in the enforcement of a federal law relating to controlled substances, drugs, or customs and who is duly authorized to possess controlled substances in the course of that person's official duties.~~

~~(e) An officer or employee of the state of Michigan, or a political subdivision or agency thereof, who is engaged in the enforcement of a state or local law relating to controlled substances and who is duly authorized to possess controlled substances in the course of that person's duties.~~

~~(2) An official who is exempted from licensure by this rule may, when acting in the course of that person's official duties, possess a controlled substance and may transfer a controlled substance to any other official who is also exempted by this rule and who is acting in the course of that person's official duties.~~

~~(3) An official who is exempted by this rule may procure a controlled substance in the course of a criminal investigation involving the person from whom the substance was procured or in the course of an administrative inspection or investigation.~~

Rule 338.3151 Inventories.

Rule Numbers	Commenter	Comment
Section (5)	Baran	Other than the beginning inventory the rule does not state the annual inventory must be kept at the licensed location. Add to " (5) A licensee shall maintain the inventory in a written, typewritten, or printed form at the licensed location. The inventory taken by use of an oral recording device ~~shall~~ **must** be promptly transcribed."
Rules Committee Response	Section (5) Baran - The Rules Committee agrees with the comment to add "at the licensed location."	

R 338.3151 Inventories.

Rule 51. (1) ~~A~~ **An individual, partnership, cooperative, association, private corporation, other legal entity, or governmental entity licensed to manufacture, distribute, prescribe, or dispense controlled substances** ~~licensee~~ shall **annually** ~~make~~ **perform** and maintain a complete and accurate inventory of all stocks of controlled substances **in the possession and control of the licensee**.

(2) The inventory ~~shall~~ **must** contain a complete and accurate record of all controlled substances in the possession or control of the licensee on the date the inventory is taken as follows:

(a) If the substance is listed in schedule 1 or 2, then the licensee shall make an exact count or measure of the contents.

(b) If the substance is listed in schedule 3, 4, or 5, then the licensee shall make an estimated count or measure of the contents, but if the container holds more than 1,000 dosage units, ~~such as tablets or capsules,~~ then the licensee shall make an accurate account of the contents.

(3) A licensee shall make a separate inventory for each licensed location on the date that he or she first engages in the activity covered by his or her license**, including a change of a pharmacist in charge**. The beginning inventory record for a licensed location shall be kept at the licensed location and a copy shall be forwarded to the ~~administrator~~ **department** upon request.

(4) A licensee shall indicate on the inventory record whether the inventory was taken ~~as of~~ **at** the opening or closing of the day that the inventory is taken.

(5) A licensee shall maintain the inventory in a written, typewritten, or printed form **at the licensed location**. The inventory taken by use of an oral recording device ~~shall~~ **must** be promptly transcribed.

(6) A licensee shall sign and date the inventory record.

(7) A licensee's printed name, address, and DEA number shall be recorded on the inventory.
(8) Schedule 2 drugs ~~shall~~ **must** be separated on the inventory from all other drugs.
(9) A licensee that is open for 24 hours shall indicate the time that the inventory was taken.
(10) On the effective date of the addition of a controlled substance to a schedule, which substance was not previously listed in any schedule, a licensee who possesses the substance shall take an inventory of all stocks of the substance on hand and incorporate it in the current inventory. Thereafter, the substance shall be included in each inventory taken.

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

Rule Numbers	Commenter	Comment
Section (a)	Baran	Voided DEA 222 forms must be kept at the licensed location see 21 CFR 1305.17. Add to **"**(a) **A licensee may keep** ~~Acquisition~~ **acquisition** records, except for executed or voided DEA 222 order forms, ~~may be~~ **in an electronic form** ~~kept~~ at a central location~~,~~ **with notice to the department.** ~~subject to the approval of the administrator~~. ~~The approval shall specify the nature of the acquisition records to be kept and the exact location where the acquisition records will be kept. All records shall be readily retrievable within 48 hours."~~
Section (b)		The rule no longer states schedule 3, 4 and 5 invoices and acquisition records must be maintained, add this back to 338.3153(b).
Section (c)	Eid	Suggestion that the term "sales receipt" be further defined to provide clarity and to explain whether sales receipts may be stored electronically or not.
Rules Committee Response	Section (a) Baran - The Rules Committee agrees with the comment to add "or voided." Section (b) Baran – The Rules Committee declines this comment as the rule already states that the records must be maintained. Section (c) Eid – The Rules Committee agrees with the comment to clarify that sales receipts may be kept electronically or in paper form, however, it does not agree that a definition of sales receipt needs to be added to the rule as receipts are adequately detailed in MCL 333.17757.	

R 338.3153 Invoices, acquisition, dispensing, administration, and distribution records.
Rule 53. ~~(1)~~ **For 2 years,** ~~A~~ **a** licensee shall ~~keep and make available for inspection~~ **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 other~~ acquisition records, ~~but excluding~~ **and** sales receipts, ~~however, a copy of each receipt shall be retained for 90 days.~~**as follows:**

(a) **A licensee may keep** ~~Acquisition~~ **acquisition** records, except for executed **or voided** DEA 222 order forms, ~~may be~~ **in an electronic form** ~~kept~~ at a central location~~,~~ **with notice to the department.** ~~subject to the approval of the administrator~~. ~~The approval shall specify the nature of the acquisition records to be kept and the exact location where the acquisition records will be kept.~~ ~~All records shall be readily retrievable within 48 hours.~~

~~(2) A licensee shall maintain acquisition records, which may be electronic, as follows:~~

~~(a)~~ **(b) A licensee shall maintain** ~~Invoices~~ **invoices** and other acquisition records of all controlled substances listed in schedules 1 and 2 ~~of R 338.3111 to R 338.3119a shall be maintained~~ in a separate file **from invoices and other acquisition records of controlled substances listed in schedules 3, 4, and 5.**

~~(b) Invoices and other acquisition records of all controlled substances listed in schedules 3, 4, and 5 of R 338.3120 to R 338.3125 shall be maintained in a separate file or in such form so that the~~ **The** information ~~required is~~ **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.

~~(3)~~ **(d)** A licensee shall initial or electronically initial the invoice and indicate the date that the controlled substances are received.

~~(4)~~ **(e)** A licensee shall keep a record, which may be electronic, of all controlled substances dispensed by him or her.

~~(5)~~ **(f)** A **licensee that** ~~prescriber~~ **prescribes controlled substances** shall keep a record separate from the patient chart which contains all of the following information for controlled substances dispensed or administered by the prescriber:

~~(a)~~ **(i)** Name of **the** patient.

~~(b)~~ **(ii)** Name **and strength** of **the controlled** substance ~~and strength~~.

~~(c)~~ **(iii)** Quantity of **the controlled** substance.

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

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

~~(6)~~ **(g)** Except in medical institutions, **a licensee shall sequentially number and maintain in chronological order the** patients' original prescriptions ~~shall be sequentially numbered and maintained in chronological order~~ as follows:

~~(a)~~ **(i)** A **licensee shall maintain a** separate file ~~shall be maintained~~ for dispensed substances listed in schedule 2 ~~of R 338.3116 to R 338.3119a~~.

~~(b)~~ **(ii)** A **licensee shall maintain a** separate file ~~shall be maintained~~ for dispensed substances listed in schedules 3, 4, and 5 ~~of R 338.3120 to R 338.3125~~.

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

prescription**,** which ~~shall become~~ **becomes** the original prescription**, the original prescription may be destroyed**. ~~Upon request of an authorized agent of the board, a paper copy of the electronic duplicate prescription shall be~~ ~~presented~~.

~~(7)~~ **(i) A licensee shall maintain records** ~~Records~~ of controlled substances distributed to another licensee, **which** shall include all of the following information and be maintained in the appropriate file described in ~~subrule~~ **subdivision** ~~(2)~~**(b)** of this rule or in a separate record that is available for inspection:

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

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

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

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

(j) A DEA 222 order form ~~shall~~ **must** be used for schedule 2 drugs.

~~(8)~~ **(k) Except for controlled substance prescriptions pursuant to subdivision (h) of this rule,** ~~Complete~~ **a licensee shall maintain** controlled substances records ~~shall be maintained or controlled by the licensee~~ for 2 years**.** ~~, except for controlled substance prescriptions, which shall be maintained for 5 years from the last date of dispensing. After 3 years, an electronic duplicate may be made of the original paper prescription which shall become the original prescription. Upon request of an authorized agent of the board, a paper copy of the electronic duplicate prescription shall be presented.~~

Rule 338.3154 Medication records in medical institutions.

Rule Numbers	Commenter	Comment
Section (5)(h)(vi)	Sapita	Regarding R338.3154 page 38 (vi) states “the name and license number” as a record requirement for pharmacists checking the automated device. We feel that it is a cumbersome requirement to have our institutional pharmacists input their license number every time they check the machines. We would like to see the verbiage requiring the “license number” to be removed completely.
Section (5)(f)(xix)(B)	Eid	Delete (B) - “The system is being used in place of an emergency kit under R 338.486(4)(c).” Rationale: In the same letter response mentioned early from the DEA to the American Society of Consultant Pharmacists in 2016, they specifically state “It also bears emphasis that, in accordance with the CSA and DEA regulations, a controlled substance may only be dispensed for emergency purposes (or otherwise) pursuant to a valid prescription. Thus, where, as in the scenario described in your letter, the kit is maintained at the LTCF by a pharmacy, controlled substances may not be

		dispensed from the kit for emergencies prior to receipt by the pharmacist of a valid prescription in accordance with the requirements of in 21 CFR §§ 1306.11 and 1306.21." Federal law differences stricter than this exemption created by the new rule will create confusion amongst licensees. To ensure compliance with the stricter federal laws, it is recommended to strike the exception for emergency kits. References: https://cdn.ymaws.com/ascp.site-ym.com/resource/collection/6F78F67D-C454-4D89-BCE1-F0C7A17755B3/November_30_DEA_Response_Letter.pdf 21 CFR 1306.11: https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_11.htm 21 CFR 1306.21: https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_21.htm
Rules Committee Response	Section (5)(h)(vi) Sapita - The Rules Committee agrees to delete "name and license number" and replace it with "identification." Section (5)(f)(xix)(B) Eid – The Rules Committee declines to delete (B) as the DEA's letter is not inconsistent with the pharmacist reviewing the prescription in 48 hours and the rule is needed for safety reasons.	

R 338.3154 Medication records in medical institutions.

Rule 54. (1) A patient's chart shall constitute a record of medications ordered for, and actually administered to, a patient of medical institutions.

(2) Medication records are required for all controlled substances listed in schedules 2, 3, 4, and 5 ~~of R 338.3116 to R 338.3125~~. At a minimum, these records ~~shall~~ **must** include all of the following information:

(a) The number of doses of controlled substances purchased.

(b) The number of doses dispensed to individual patients or distributed to nursing stations or both.

(c) The number of doses administered.

(d) The number of doses dispensed, but not administered, to the patient.

~~(e) An annual physical inventory and status of any discrepancies between the inventory and the records of acquisition and the dispensing records.~~

(3) If the controlled substance is not dispensed to an individual patient, all of the following provisions ~~shall~~ **must** be complied with:

(a) Medication records for those controlled substances in schedules 2, 3, 4, and 5 ~~of R 338.3116 to R 338.3125 shall~~ **must** be maintained.

(b) Distribution of a controlled substance to a nursing unit ~~shall~~ **may** not be more than 25 doses per container.

(c) A distribution record for each multiple of 25 doses ~~shall~~ **must** be used to account for delivery to a nursing unit. The record ~~shall~~ **must** include all of the following information:

(i) The name and dose of the controlled substance.

(ii) The quantity of the substance.

(iii) The date of delivery.

(iv) The location of the nursing unit.

(v) The name of the distributing pharmacy and address if a different location from the medical institution.

(vi) Name of distributing pharmacist.

(vii) The name of the individual on the nursing unit who receives the substance.

(d) A proof of use record ~~shall~~ **must** be maintained to account for all doses of an administered substance. The record ~~shall~~ **must** include all of the following:

(i) The name of the substance.

(ii) The dose administered.

(iii) The date and time a dose was administered.

(iv) The name of the patient.

(v) The signature of the individual who administered the dose.

(e) Subrule 3 of this rule does not apply to automated ~~dispensing~~ devices.

(4) A controlled substance that is maintained at a nursing unit must be stored in a securely locked cabinet or medication cart that is accessible only to an individual who is responsible for the administration or distribution of the medication.

~~(4)~~ **(5)** If a controlled substance ~~or any medication or device~~ is dispensed from an automated device, then documentation ~~as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility~~ **of all of the following** ~~shall~~ **must** be maintained on-site in the pharmacy **responsible for the automated device for 2 years** for review by the department**, an agency, or the board:** ~~. When patient medication is stocked in an automated device, the pharmacy responsible for the device shall obtain an additional controlled substance license for each hospital, county medical care facility, nursing home, hospice, or other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109, when the pharmacy is not located at the same address as the facility and controlled substances are dispensed from the automated device. The documentation shall include at least all of the following information:~~

(a) ~~Name~~ **The name** and address of the pharmacy or facility responsible for the operation of the automated device. ~~Manufacturer name and model number.~~

(b) The manufacturer, serial number, and model number of the automated device.

(c) The location of the automated device.

(d) The contents of the automated device.

~~(c)~~ **(e) The** ~~Quality~~ **quality** assurance policy and procedure to determine continued appropriate use and performance of the automated device~~.~~ **that includes all of the following quality assurance documentation for the use and performance of the automated device:**

(i) Use of monitors that alert the user when the wrong medication is filled or removed for administration to a patient.

(ii) Use of security monitors that include an alert for unauthorized access, patients not in the system, system security breaches, and controlled substance audits.

(iii) Corrective measures to address issues and errors identified in the internal quality assurance program.

~~(d)~~ **(f) The** ~~Policy~~ **policy** and procedure for system operation that includes all of the following:

(i) Safety.

(ii) Security **systems and procedures that include prevention of unauthorized access or use and comply with federal and state regulations.**

(iii) Accuracy.

(iv) Patient confidentiality.

(v) Access.

(vi) **Type of** ~~Controlled~~ **controlled** substances.

(vii) Data retention or archival.

(viii) Definitions.

(ix) Downtime procedures.

(x) Emergency procedures.

(xi) ~~Inspection~~ **Operator inspections.**

(xii) Installation requirements.

(xiii) Maintenance.

(xiv) Medication security.

~~(xv) Quality assurance.~~

(~~xvi~~**xv**) Medication inventory.

(~~xvii~~**xvi**) Staff education and training.

(~~xviii~~**xvii**) System set-up and malfunction.

(~~xix~~**xviii**) List of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.

(xix) The use of the automated device that includes a requirement that a pharmacist review a prescription or medication order before system profiling or removal of any medication from the automated device for immediate patient administration, except in the following situations where a pharmacist shall review the orders and authorize any further dispensing within 48 hours:

(A) The automated device is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist under R 338.486(4)(j).

(B) The system is being used in place of an emergency kit under R 338.486(4)(c).

(C) The system is being accessed to remove medication required to treat the emergent needs of a patient under R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.

~~(5) Automated devices shall have adequate security systems and procedures, evidenced by written pharmacy policies and procedures that document all of the following information: Prevention of unauthorized access or use. Compliance with any applicable federal and state regulations. Maintenance of patient confidentiality.~~

~~(6)~~ **(g)** ~~Records and electronic data kept~~ **The automated device must maintain transaction data that includes all** ~~by automated devices shall meet all of the following requirements:~~

~~(a) All events involving~~ **activity regarding** access to the contents of the automated **device** ~~devices shall be recorded electronically~~.

~~(b)~~ **(h) The pharmacy responsible for the automated device shall maintain records related to access to the automated device. The records must** ~~Records shall be maintained by the pharmacy responsible for the device and shall~~ be readily retrievable~~. The records~~ **and** ~~shall~~ **must** include all of the following information:

(i) The unique identity of **the** device ~~accessed~~.

(ii) Identification of the individual accessing the **automated** device.

(iii) The type of transaction.

(iv) The name, strength, dosage form**,** and quantity of the drug accessed.

(v) The name of the patient ~~for whom the drug was ordered~~.

(vi) ~~Identification~~ **The** ~~**name and license number**~~ **identification** of the pharmacist checking for the accuracy of the medications to be stocked or restocked in the **automated** device.

~~(vii) If the pharmacist delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that is in compliance with R 338.490. This subdivision takes effect April 11, 2003.~~

(vii) **Any other** ~~Additional~~ information ~~as~~ the pharmacist ~~may deem~~ **considers** necessary.

(i) For medication removed from the automated device for on-site patient administration, the automated device must document all of the following information:

(i) The name of the patient.

(ii) The date and time medication was removed from the automated device.

(iii) The name, initials, or other unique identifier of the individual removing the drug.

(iv) The name, strength, and dosage form of the drug. The documentation may be on paper or electronic medium.

(j) If the pharmacist delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing bar-coding or another a board-approved error prevention technology.

~~(7) For medication removed from the system for on-site patient administration, the system shall document all of the following information:~~

~~(a) The name of the patient.~~

~~(b) The date and time medication was removed from the device.~~

~~(c) The name, initials, or other unique identifier of the person removing the drug.~~

~~(d) The name, strength, and dosage form of the drug. The documentation may be on paper or electronic medium.~~

~~(8)~~ **(k)** The automated device ~~shall~~ **must** provide a mechanism for securing and accounting for **controlled substances** ~~medications once~~ removed from ~~and subsequently returned to,~~ the automated device return bin. ~~Neither~~ **Controlled substances** ~~medication nor a device~~ may **not** be returned directly to the ~~system~~ **automated device** for immediate reissue or reuse. **Controlled substances** ~~Medication or devices once~~ removed **from the automated device** ~~shall~~ **may** not be reused or reissued, except as indicated in R 338.486(7).

~~(9)~~ **(l)** The automated device ~~shall~~ **must** provide a mechanism for securing and accounting for wasted or discarded medications.

~~(10) The internal quality assurance documentation for the use and performance of the automated device shall include at least all of the following:~~

~~(a) Safety monitors that include wrong medications removed and administered to patient.~~

~~(b) Accuracy monitors that include filling errors and wrong medications removed.~~

~~(c) Security monitors that include unauthorized access, patients not in the system, system security breaches, and controlled substance audits.~~

~~(d) Policies that establish corrective measures taken to address the problems and errors identified in the internal quality assurance program and its integration to the overall quality assurance policies.~~

~~(11) Policy and procedures for the use of the automated device shall include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:~~

~~(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(i).~~

~~(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).~~

~~(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.~~

~~(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.~~

~~(12) A copy of all pharmacy policies and procedures related to the use of an automated device shall be maintained at the pharmacy responsible for the device's specific location and be available for review by an agent of the board.~~

~~(13) A controlled substance that is maintained at a nursing unit shall be stored in a securely locked cabinet or medication cart that is accessible only to an individual who is responsible for the administration or distribution of the medication.~~

~~(14) Records and documents required under this rule shall be maintained or controlled by the pharmacy responsible for the device for 2 years.~~

~~(15)~~ **(6)** An individual who is responsible for administering a controlled substance or a portion thereof shall record the quantity, disposition and an explanation of the destruction of the controlled substance on the proper accountability record. If the institution has a policy that reflects current practice standards and delineates the method of destruction, an explanation would only be required if policy was not followed.

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

Rule Numbers	Commenter	Comment
R 338.3162a	Eid	Generally, states do not place the burden upon the pharmacist to determine whether the controlled substance prescription correctly falls under an exception to the requirements to electronically prescribe. There is currently language within MCL 333.17754a (8) that provides for a route for pharmacist to exercise their judgement without having to determine whether an exception applies. Arkansas, California, Iowa, Kansas, Kentucky,

		Missouri, Nevada, New York, South Carolina, Tennessee, and Virginia are just some of the states that have imposed electronic prescribing requirements on prescribers but have continued to allow pharmacists to dispense all otherwise lawful prescriptions, regardless of format. It may not be needed to copy the statute language within the rule unless the Department/Board sees fit for clarity. References: http://www.legislature.mi.gov/(S(pjk3ae1byhmej1ecdz4nz1wl))/mileg.aspx?page=getObject&objectName=mcl-333-17702
	Cargill	Please clarify in Rule if the intention the Act's reference to an exemption for "A Hospice" includes both a hospice residence and hospice agency. The act specifically references an exception for a hospice facility, and thus we are reasonably certain this provision in the Act means a hospice "residence facility". However, other references in MILARA Health Facility Rules have defined "A Hospice Facility" to include "a hospice agency". MILARA's clarification in Rule on this definition would be helpful for prescribers working with hospice patients in their residence. In addition, prescribers prescribing in a hospice will benefit from Rule clarification of the intent and meaning of language in this section requiring a "prescription must be issued and dispensed in the same health care facility". There are hospice prescribers who wish to apply for this waiver, including some that have already requested a waiver to the department, despite the required form not being unavailable. The non availability of the required FORM has created uncertainty for hospices with technical and rural challenges who wish to apply for and receive the allowed waiver. We agree with the two-year period for a qualified waiver and request the waiver form be produced and made available to prescribers as soon as possible. This would provide prescribers having appropriate rational for receiving a waiver to apply and have reasonable certainty if they will qualify and receive the waiver. We further request that the effective date of the Act and penalties be delayed one year to October 1, 2022, or the final date required by the federal Centers for Medicare and Medicaid Services. We further request that if the Department does not have discretion to delay implementation by Rule, that the Department request the Legislature to act to delay implementation and/or related penalties before October 1, 2021. The non availability of the required FORM has created uncertainty for hospices with technical and rural challenges who wish to apply for and receive the allowed waiver.
Sections (4) and (5)	Young	Request clarification be added to the rules as to whether a hospice is an automatic exemption to transmitting a prescription electronically of if an application for a waiver will be required.
Sections	Mankowski	The effective date of this rule states October 1, 2021 (or appropriately the statutory delay

(1),(4), and (5)		based on CMS's electronic transmission requirement for Medicare). The General Rules for pharmacy have updated this date to January 1, 2022 and the same should be done in this ruleset.
Sections (1) and (4)	Novak	Under subrules (1) and (4), MSMS encourages the Department to ensure the dates in the Proposed Rule Set and the proposed Pharmacy – General Rules align with Public Acts 134, 135 and 136 of 2020. For this purpose, MSMS recommends that subrule (4) be amended to recognize the exceptions to electronic transmissions permitted by MCL §333.17754a, as follows: (4) Effective October 1, 2021, or the date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, whichever occurs later, prescribers shall, unless an exception under section 17754a of the 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. MSMS also recommends subrule (5)(b)(iv) be amended to identify examples of qualifying "exceptional circumstances, as follows:" (iv) The prescriber demonstrates attests to exceptional circumstances including, but not limited to, the following: A. Prescribing fewer than "X" prescriptions (combined controlled and non-controlled substances) per year. B. Utilizing electronic transmission for non-controlled substances, but prescribing fewer than "Y" controlled substance prescriptions per year. (Note: The cost of the enhanced e-prescribing software for controlled substances is not fiscally responsible for some prescribers who rarely prescribe them.) C. Intention to cease practice within the next twelve months. D. Limited practice due to an illness or other unforeseen event.
Section (4)	Carlson	To provide consistency between the Rules and Code and to avoid confusion, the MHA recommends stating electronic transmission exceptions are allowed in Michigan in certain instances. Therefore, the MHA agrees with other healthcare stakeholders that R 338.3162a (4) should be amended to the following: (4) Effective October 1, 2021, or the date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, whichever occurs later, prescribers shall, unless an exception under section 17754a of the 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.
Section (5)(b)(iv)	Carlson	As well as clarifying language in subrule (5)(b)(iv) "The prescriber demonstrates attests to exceptional circumstances including, but not limited to, the following…" The word "demonstrates" indicates there will be a process in place where a prescriber will need to submit tangible evidence. However, we believe the intent was for the provider to declare or formally certify in writing. An attestation should suffice with the department's ability to follow up.
Rules Committee Response	(1), (4), and (5) Mankowski, Carlson, and Novak – The Rules Committee agrees that the language in this rule should be consistent with both the Pharmacy General rules and the Code. There are three areas in this rule that should be modified for consistency: • The effective date: The Public Health Code mandates electronic transmission of prescriptions as of October 1, 2021, but requires that the Department delay the implementation date of the mandate to the date established by the Federal Centers for Medicare and Medicaid Services for electronic transmission of prescription for controlled substances. Therefore, the Rules Committee recommends that the effective date be deleted and the mandate be enforced on the date the mandate is enforced by the Federal Centers for Medicare and Medicaid Services.	

R 338.3162a Electronic transmission of ~~prescriptions~~ **prescription**; **waiver of electronic transmission**~~"electronically transmitted prescription drug order" defined~~.

Rule 62a. ~~(1) As used in this rule, "electronically transmitted prescription drug order" means a prescription drug order that is communicated from the prescriber directly to the pharmacy by electronic means, so that the data cannot be altered, modified, extracted, viewed, or manipulated in the transmission process.~~

~~(2)~~ **(1) Until ~~October 1, 2021, or~~ the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement~~, whichever occurs later,~~ a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription if all of the following conditions are satisfied:**

(a) The ~~An electronically transmitted~~ prescription ~~order shall be~~ **is** transmitted to the pharmacy of the patient's choice and ~~shall occur~~ **occurs** only at the option of the patient.

~~(3) A pharmacist may dispense an electronically transmitted prescription drug order only if both of the following conditions are satisfied:~~

~~(a)~~**(b)** The electronically transmitted prescription ~~drug order~~ 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.

~~(vi)~~**(vii)** All other information that ~~is required to~~ **must** be contained in a prescription under ~~the provisions of~~ R 338.3161.

~~(b)~~ **(c)** The pharmacist exercises professional judgment regarding the accuracy or authenticity of the transmitted prescription. Technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement.

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

~~(4)~~ **(2)** An electronically transmitted prescription ~~drug order~~ that meets the requirements of subrule ~~(3)~~ **(1)** of this rule ~~shall be deemed to be~~ **is** the original prescription.

~~(5)~~ **(3)** This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions.

(4) Effective ~~October 1, 2021, or~~ on the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement~~, whichever occurs later,~~ ~~An~~ **prescribers shall 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.

(5) 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 all of the following requirements:

(a) The prescriber is unable to meet the requirements of section 17754a(1) ~~and~~ or (2) of the code, MCL 333.17754a.

(b) The prescriber meets 1 of the following:

(i) The prescriber provides evidence satisfactory to the department that he or she has received a waiver of the Medicare requirements for the electronic transmission of controlled substances prescriptions at the federal Centers for Medicare and Medicaid Services.

(ii) The ~~prescriber and dispensing pharmacy are the same entity~~ prescription is dispensed by a dispensing prescriber.

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

(iv) The prescriber demonstrates exceptional circumstances.

(v) The prescriber issues prescriptions from a non-profit charitable medical clinic.

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

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

Rule Numbers	Commenter	Comment
Sections (1)(e), (l), and (m)	Sapita	Regarding R 338.3162b subsection 1(e) which specifies patient/client gender, subsection 1(l) which specifies "number of refills authorized', and subsection 1(m) which specifies "refill number of prescription fill". We question the need to include gender in the reporting requirements. We believe that that the inclusion of these subsections requires additional unnecessary efforts on the pharmacy to comply. For example, a pharmacist knows that if a prescription comes in for a schedule II there would be no authorized refills, yet to comply with the administrative rules as drafted, would have to report 0 refills. We ask that these reporting requirements be removed from the administrative rules.
Section (1)(q)	Mollien	The rules do not address or provide clarity for a definition of what a "cash" transaction is for purposes of reporting "the prescription payment type" under R 338.3162b(1)(q). The rule should add a definition or explain what payment types are considered "cash" under the ASAP 4.1 reporting requirements, which should include cash prices at U&C and, only for purposes of reporting to MAPS, any discount card used that is not regulated under the Insurance Code (e.g. GoodRx, etc.)
Rules Committee Response	The Rules Committee	

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~~ a** pharmacist, dispensing prescriber, and veterinarian licensed under Part 177 **of the code, MCL 333.17701 to 333.17780,** who dispenses a prescription drug

~~which~~ **that** is a controlled substance listed in schedules 2 to 5 or a pharmacy licensed by the 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 ~~schedules~~ **scheduled** 2 to 5 controlled substance ~~prescription~~ **that has been** dispensed:

(a) The patient identifier **identification number**~~, as defined in R 338.3102(1)(f)~~. **For purposes of this subdivision, all of** ~~The~~ **the** following apply:

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

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

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

(b) ~~The name of the controlled substance dispensed.~~ **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.

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

~~(d)~~ **(i)** The ~~national drug code number (ndc)~~ **NDC** of the controlled substance dispensed.

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

~~(f)~~ **(k)** The date of dispensing.

(l) The number of refills authorized.

(m) The refill number of the prescription fill.

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

~~(h)~~ **(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.

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

(s) The patient's or client's location code when receiving pharmacy services, as specified by ASAP.

~~(i)~~ **(t)** The ~~(dea)~~ **DEA** registration number of the prescriber and the dispensing pharmacy.

~~(j) The Michigan license number of 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 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 an individual, not an animal.

Rule 338.3163 Drug-dependent individual; prescribing, dispensing, and administering controlled substance.

Rule Numbers	Commenter	Comment
R 338.3163	Novak	MSMS believes that Rule 63 be eliminated or significantly revised for better clarity and consistency with federal law. This proposed Rule is confusing and uses terminology that is inconsistent with similar federal laws regarding the authorized prescribing, administering and dispensing of controlled substances to an individual for treatment of substance use disorder. For example, the proposed Rule fails to recognize that while not all "licensed health professionals" are "prescribers," all prescribers are licensed health professionals. Accordingly, the proposed Rule's application of contradictory standards for "prescribers" and "licensed health professionals" creates confusion for the scope of authority of physicians and other prescribers to treat an individual for substance use disorder, and negatively impacts access to substance use disorder treatment. Furthermore, the term "drug-dependent individual" is not defined in the Proposed Rule Set and is not acknowledged by the Public Health Code. MSMS questions whether there is a more appropriate and person-first reference to these individuals than "drug-dependent individual." To the extent the Department seeks consistency with standards established by federal law and regulations, MSMS recommends the Department specifically incorporate by reference such federal laws and regulations.
Rules Committee	The Rules Committee	

Response	

R 338.3163 Drug-dependent ~~person~~ **individual**; prescribing, dispensing, and administering controlled substance.

Rule 63. ~~(1)~~ A **licensee** ~~prescription~~ shall not ~~be issued~~ **prescribe, dispense, or administer** ~~for~~ a controlled substance ~~nor shall a controlled substance be dispensed or administered~~ to a drug-dependent ~~person~~ **individual** for the purpose of continuing his or her drug dependency, except as follows:

(a) A prescriber, licensed ~~in accordance with~~ **pursuant to** federal ~~and state~~ law to conduct the drug treatment of a drug-dependent ~~person~~ **individual** ~~in a program~~ may **within his or her scope of practice** prescribe, **dispense, and administer** a controlled substance for the purpose of legitimate treatment of the drug-dependent ~~person~~ **individual**. **A prescription may only be issued for a schedule 3 through 5 substance.**

(b) A **licensed health professional within the scope of his or her practice may administer or dispense a** controlled substance ~~may be administered or dispensed, or both, by a dispenser,~~ directly to a drug-dependent ~~person~~ **individual** for the purpose of continuing his or her dependence ~~who is enrolled in a drug treatment and rehabilitation program.~~ **consistent with both of the following requirements:**

(i) The drug-dependent individual is in 1 of the following situations:

(A) The drug-dependent individual is participating in a drug treatment and rehabilitation program.

(B) The drug-dependent individual is experiencing acute withdrawal symptoms and administration of a controlled substance is necessary while the licensed health professional is arranging referral for treatment. The following requirements must be followed:

(I) Not more than 1 day's supply of medication may be administered or directly dispensed to the drug-dependent individual.

(II) The emergency treatment may be carried out for not more than 3 consecutive days and may not be renewed or extended.

(ii) The controlled substance must be approved by the FDA specifically for use in maintenance or detoxification treatment.

(~~2~~**c**) A **licensed health professional within the scope of his or her practice** ~~controlled substance~~ may ~~be prescribed~~ **administer** ~~or dispensed~~ **a controlled substance** ~~in an acute care hospital to continue maintenance treatment for drug dependency for a patient whose hospitalization is for treatment of a medical condition other than addiction. The enrollment of the patient in an approved maintenance treatment program shall be verified.~~ **to a drug-dependent individual consistent with both of the following:**

(i) The licensed health professional is administering a controlled substance to continue maintenance or detoxification treatment as an adjunct to medical or surgical treatment of conditions other than addiction.

(ii) The licensed health professional is administering a controlled substance to relieve intractable pain for which no relief or cure is possible, or none has been found after reasonable efforts.

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

Rule Numbers	Commenter	Comment
Section (2)(c)	Sapita	Regarding R338.3165 subsection 2(c) which specifies "dispensing pharmacist". We believe this would cause undue hardship on our relief pharmacists who may work at different pharmacies each day. Would the dispensing relief pharmacist have to check each place of work to ensure compliance with this rule?
Rules Committee Response	The Rules Committee	

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

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

(a) The prescriber shall deliver to the dispensing pharmacist a written prescription or electronically transmit the prescription pursuant to R 338.3162a. ~~reduce the prescription to writing and have recorded on the~~

(b) The prescriber shall include on the ~~prescription's face~~ **prescription both** "Authorization for Emergency Dispensing" and the date of the oral order. ~~The written prescription shall be delivered to the pharmacist in person or by mail within 7 days after the oral prescription is issued.~~

(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 dispensing pharmacist shall attach ~~this~~ **the** prescription to the oral order which **was** earlier ~~had been~~ reduced to writing.

(c) The **dispensing** pharmacist shall notify the department ~~of consumer and industry services~~ if the prescriber fails to deliver **to him or her either** a written prescription **or a prescription transmitted electronically** ~~to him or her~~.

(3) The failure of a pharmacist to notify the department if the prescriber fails to deliver a ~~written~~ prescription **pursuant to subrule (1) of this rule** voids the authority conferred by this rule ~~to dispense without a written prescription of a prescriber~~.