MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
SEPTEMBER 24, 2021

The Michigan Board of Pharmacy Rules Committee Work Group met on September 24, 2021. The meeting was held via Zoom.

CALL TO ORDER

Andria Ditschman called the meeting to order at 8:06 a.m.

ATTENDANCE

Members Present: Pierre Boutros, R.Ph. (arrived 8:45 a.m.)
Charles Mollien, PharmD, JD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph. (left 11:11 a.m.)

Members Absent: None

Staff Present: Andria Ditschman, Senior Policy Analyst, Boards and Committees Section
Jacob Poynter, Manager, Licensing Division
Stephanie Wysack, Board Support, Boards and Committees Section

Public Present: Kendra Croker, PharmD, MVA, RPh - TelePharm
Deeb Eid - CVS Pharmacy
Stacey Hettiger – Michigan State Medical Society
Brian Sapita – Government Affairs Manager, Michigan Pharmacists Association (MPA)
Kathleen Westfall – Legal Counsel, Michigan State Medical Society

RULES DISCUSSION

Ditschman explained that she would continue to review the comments received from the public hearing that was held on the Controlled Substance draft rules on September 9, 2021 and then move onto the comments received from the public hearing that was held on the General Rules on September 21, 2021. She stated that the Rules Committee's recommendations would be added to the public comment summaries 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).

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

Eid comment: Ditschman stated that the commenter requested that rule be removed so as not to further limit the pharmacist. The statute already allows for the pharmacist to use their professional judgment.

Mollien stated that this is not new language and to remove it would cause the rule to no longer make sense.

Discussion was held.

The Rules Committee rejected the comment, indicating that the criteria was needed.

Cargill and Young comments: Ditschman stated that both commenters asked for clarification of the term "hospice."

Ditschman stated that it is defined in the statute under Article 17.

Discussion was held.

The Rules Committee rejected the comment as the term "hospice" is defined in the statute.

Section (1) and (4):

Novak comment: Ditschman stated that the commenter asked for clarification of the exceptions.

The Rules Committee agreed with the comment.

Section (5)(b)(iv):

Novak comment: Ditschman read the comment.

Hettiger explained that the commenter was asking for context to be provided as to what types of exceptional circumstances there could be.

Ditschman stated that the statute did not allow for the rules to be more restrictive than the federal Centers for Medicare and Medicaid Services (CMS).

Discussion was held regarding the cost of electronic transmission software, frequency of prescribing, and security issues with paper prescriptions versus electronic.

The Rules Committee agreed with the addition of (5)(b)(iv)(A)(C) and (D).

The Rules Committee also agreed to changing the word “demonstrates” to “attests.”

Discussion was held on what number to use for “X” under (B).

Hettiger suggested using “fewer than 100 or a number consistent with CMS.”

The Rules Committee agreed with the suggested language to (B).

Section (4):

Carlson comment: Ditschman stated that the above change to the use of the word “attests” addressed this comment.

The Rules Committee agreed.

Section (5)(a) and (b)(ii): Ditschman stated that these sections need to be modified to be consistent with the statute, and as there were comments asking for consistency with the Code and Pharmacy General Rules. The changes would be recommended to the Board.

The Rules Committee agreed with the language change as presented.

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

Section (1)(e) and (m):

Sapita comment: Sapita explained that the request came from the undue burden that is caused when entering the gender for each refill.

Ditschman indicated that the Department stated that this was not a new requirement and that other states also require the information.

Discussion was held.

The Rules Committee rejected the comment as the information was needed for prescription matching.

Section (1)(q):

Mollien comment: Mollien explained that his comment would clarify how discount cards would be entered in order to be more accurate in reporting to MAPS. He suggested adding the phrase "cash discount cards are considered cash transactions."

Discussion was held.

The Rules Committee agreed to the added language.

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

Novak comment: Ditschman stated that this comment was related to the comment made for R 338.3137, eliminating the Drug Treatment Prescriber license.

Hettiger made the following suggestions to the MSMS comment:
*Use the phrase "individual with drug addiction" instead of "drug-dependent individual." Hettiger will follow up with those who work in the substance use area to find out what the proper term is for this situation. She will get back in touch with Ditschman.
*Address what can be done instead of what cannot be done.
*Use the word "practitioner" instead of "prescriber" to follow federal language.

Ditschman stated that the above suggestions provided clarification and were not substantive changes.

The Rules Committee agreed to the use of clarifying language.

Hettiger to send exact wording to Ditschman.

Section (1)(b)(i)(A): Hettiger stated that the phrase "drug treatment and rehabilitation program" was not defined by the federal rule and that it should either be removed or clarified.

Westfall stated that (A) and (B) contradict each other as currently written.

Discussion was held.

Ditschman read the definition of a program as defined in the code under MCL 330.1260. She stated that the rule was written to not be restrictive to drug treatment programs.

The Rules Committee agreed with the comment and added the definition of a program from the code.

Section (1)(c): Westfall stated that this section causes confusion with administering.

Mollien stated that the rule was written so that only (a), (b), or (c) has to be met, not all.

Discussion was held.

Ditschman will check the federal regulations to confirm consistency and to see if additional language would help differentiate the section in the rule.

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

Section (2)(c):

Sapita comment: Mollien stated that changing language to "the pharmacy" would address the comment.

Sleiman stated that this was not common practice.

Discussion was held regarding whether the pharmacy or the pharmacist should be responsible.

The Rules Committee agreed with the comment and will change the phrase "dispensing pharmacist" to "the pharmacy."

Ditschman stated that the change also applied to section (3).

Pharmacy – Pharmacy – General Rules, Public Comment Summary (A copy of the draft, used during discussion, is attached).

R 338.501 Definitions.

Section (1): Mollien stated that clarifying that the word "written" allows for paper makes sense throughout the rule when used.

The Rules Committee agreed with the comment.

R 338.505 Inspection of applicants and licensees.

Section (2) Sapita comment: Ditschman stated that this section was added by the Department to address concerns that the Department would be looking at business information in inspections. The language will clarify that the business information would not be considered during a prelicensure inspection.

Mollien stated that the intent is for the information to be available as part of an investigation, not in obtaining licensure.

The Rules Committee agreed to add the following language: “Inspections in provision (1) must not extend to any of the following information, however, the information is subject to a disciplinary investigation.”

The Rules Committee agreed to the comment and language modification.

R 338.523 Pharmacist license by endorsement; requirements.

Section (2)(a)(ii):

Sapita comment: Ditschman stated that allowing for licensure from Canadian licensed pharmacists was statutory and could not be changed. What could be changed was the acceptance of the Canadian examination.

The Rules Committee agreed and rejected the comment for that reason.

R 338.531a Remote pharmacy waiver from mileage requirement.

Section (2)(b):

Eid comment: Ditschman read the comment.

The Rules Committee agreed with the comment.

Section (2)(c)(i):

Sapita comment: Mollien stated that these should continue to be reviewed by the Board.

Discussion was held.

The Rules Committee rejected the comment as the rule should stay broad to not limit access.

Section (2)(c)(ii): Ditschman read the comment.

The Rules Committee rejected the comment as the rule should stay broad to not limit the possible services.

Section (2)(a):

Croker comment: Croker stated that a map is redundant as it was asked for under R 338.531(2)(k)(iii).

Discussion was held.

The Rules Committee rejected the comment as the map was a necessary piece of information when considering a waiver request.

Section (2)(c)(ii) and (iii):

Croker comment: Croker stated that this rule was limiting and should be removed to allow for better access to pharmacy services.

Discussion was held regarding the rule being broad enough to allow for accessibility to be covered using the word “unique.”

The Rules Committee rejected the comment, stating that the rule was broad enough.

R 338.534 Inspections.

Section (3):

Pritchett comment: Ditschman read the comment requesting the rule to go back to requesting “either” accreditation or an inspection, changing the 18-month requirement, and allowing virtual inspections.

Poynter stated that the Department had been accepting evidence of accreditation, without an inspection report, during the pandemic, but are no longer doing so at this time.

Discussion was held regarding the timeframe being either 18-months, the same as ACHC, or leaving it at two years, as requested in the rule as written.

The Rules Committee rejected increasing the timeframe.

Discussion was held regarding allowing virtual inspections.

Mollien stated that the phrase “on site physical” would need to be removed to accommodate accepting the inspection in the format that the entity deemed appropriate.

The Rules Committee agreed to the change in language, which would allow for virtual inspections as the Board reviews the accrediting organizations. If an organization did not provide appropriate virtual inspections, then their ability to do the inspections can be revoked by the Board.

R 338.561 Pharmacy as wholesale distributor; licensure.

Sections (a) through (d):

Mollien comment: Ditschman stated that the rule was written to accommodate for all of the exceptions in the federal regulation.

Mollien agreed and withdrew his comment.

R 338.563 Wholesale distributor; wholesale distributor-broker; application for licensure; requirements.

Section (2)(h):

Mollien comment: Ditschman stated that she was unable to find a requirement in federal law for an FDA certification for a wholesale distributor who was distributing biologicals and, therefore, the rule could be removed.

Discussion held.

The Rules Committee agreed to remove the rule.

R 338.569 Wholesale distributor and wholesale distributor-broker recordkeeping and policy requirements.

Section (4):

Mollien comment: Ditschman asked where the requested record keeping requirements would be placed in the rules.

Discussion held.

The Board agreed to include the requirement in a new section (8). Mollien will provide the specific language to Ditschman.

ADJOURNMENT

Ditschman stated that another Rules Committee Work Group would need to be scheduled in order to finish the Pharmacy – General Rules Public Comment Summary prior to the October 1, 2021 board meeting.

Ditschman adjourned the meeting at 11:30 a.m.

Prepared by:
Stephanie Wysack, Board Support September 30, 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
Charlie Mollien
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
	Lambert	Objected to controlled substances being limited to a certain amount as doctors are afraid to prescribe medicines.
Rules Committee Response	There is no recommendation as this does not relate to the rules.	

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 ramifications to adding this exception to the licensing requirement is not clear at this time and may not be 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.~~

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.

(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) 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.

~~**(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** aseparate 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	Carlson	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 (1),(4), and (5)	Mankowski	The effective date of this rule states October 1, 2021 (or appropriately the statutory delay 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.
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.
Section (5)(b)(iv)	Novak	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.
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. • *The requirement that a prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code.* A typographical error that requires a prescriber to meet both (1) and (2) should be changed to (1) or (2) for consistency with the Pharmacy General Rules and the Code. • *A dispensing prescriber*: In the Pharmacy General Rules the basis for a waiver that "the prescriber and dispensing pharmacy are the same entity" was modified in the Controlled Substances rules to "if the prescription is dispensed by a dispensing prescriber." • *CMS waiver is automatic state waiver*: The Code requires that if a CMS waiver is granted then the Department shall grant a waiver, so provision (5) should be modified to allow for this waiver without meeting other requirements. Therefore, (5) will be reorganized.	

	• *Professional judgment:* Modify (1)(c) for consistency with the Code and Pharmacy General Rules. • The Controlled Substances Rules include the following provision which is not in the Pharmacy General Rules. For consistency it should be deleted from the CS rules or added to the General rules unless there is a valid reason to differentiate between a CS and non CS prescriptions. "This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions." Section (1) Eid – The Rules Committee does not recommend that the following be deleted "a pharmacist may dispense the electronically transmitted prescription if all of the following conditions are satisfied: ….", as the Rules Committee believes the requirements should remain for the pharmacist. Section (4) – The Rules Committee agrees with the comments that the rules should be amended to recognize the exceptions to electronic transmissions permitted by MCL §333.17754a. Hospice – The Rules Committee does not recommend that the rules define "hospice" or clarify what is meant by "hospice" in the Code, as the terms defined in the Code have the same meaning when used in these rules. The term "hospice" is defined in section 20106(4) of the Code, MCL 333.20106, as "a health care program that provides a coordinated set of services rendered at home or in outpatient or institutional settings for individuals suffering from a disease or condition with a terminal prognosis." In addition, Part 214 of the Code states that "the term hospice shall not be used to describe or refer to a health program or agency unless that program or agency is licensed as a hospice by the department as required under this article or is exempted from licensure as provided in subsection (5)." Therefore, "hospice" is already defined by the Code. Section (5)(b)(iv) Novak – The Rules Committee agrees with the suggested language, except, it does not recommend adding (B) and would suggest modifying (A) to: 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 waiver for electronic transmission of prescriptions for controlled substances, whichever is less. Section (5)(b)(iv) Carlson – The Rules Committee agrees with the comment to add "attests" instead of "demonstrates."

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**, validity,** ~~or~~ **and** 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, 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.

(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 either ~~all~~ 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.

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

(i) The ~~prescriber and dispensing pharmacy are the same entity~~ 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) 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 waiver for electronic transmission of prescriptions for controlled substances, whichever is less.

(B) Intention to cease practice within the next twelve months.

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

(iv) 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	Section (1)(e), (l), and (m) Sapita - The Rules Committee declines the comment as this information is already reported. Section (1)(q) Mollien – The rules Committee agrees that it would be helpful to those reporting information to know that cash discount cards are considered cast transactions.	

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. 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 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 Response	Novak: The Rules Committee recommends the following changes consistent with the suggested comments: • Drug dependent person be modified to person dependent on narcotics. • The various terms, licensee, health professional, and prescriber, be modified for consistency to licensed health professional. • Modify the rule to state the behavior that is allowed instead of what is prohibited. • Modify "drug treatment and rehabilitation program", which is not defined in the Code, to "program" as that term is defined in the Mental Health Code, MCL 330.1260(1)(i)**.**	

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

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

(a) A ~~prescriber~~ **licensed health professional**, licensed ~~in accordance with~~ **pursuant to** federal ~~and state~~ law to conduct the ~~drug treatment~~ **maintenance or detoxification treatment** of a ~~drug-dependent~~ person **dependent on narcotics** ~~**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 **dependent on narcotics ~~individual~~ consistent with 21 CFR 1301.28. 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 **dependent on narcotics ~~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~~ person dependent on narcotics is in 1 of the following situations:

(A) The ~~drug-dependent individual~~ person dependent on narcotics is participating in a ~~drug treatment and rehabilitation program~~ program defined in section 260(1)(i) of the Mental Health Code, MCL 330.1260.

(B) The ~~drug-dependent individual~~ person dependent on narcotics 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~~ person dependent on narcotics.

(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~~person dependent on narcotics 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	Section (2)(c) Sapita - The Rules Committee agrees that the term “dispensing pharmacist” and “pharmacist” should be modified to “pharmacy.”	

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~~ **the pharmacy** 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~~ **the pharmacy** 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~~.

Pharmacy General Rules - ORR 2020-128 LR
Public Comment Summary
Rules Committee's Recommendations to September 21, 2021 Public Comments

Testimony/Comments Received:

Rose M. Baran, PharmD
Deeb D. Eid, PharmD, RPh, Advisor, Pharmacy Regulatory Affairs, CVS Health
Charlie Mollien
Julie L. Novak, Chief Executive Officer, Michigan State Medical Society (MSMS)
Jon Pritchett, Pharm D., RPh., BCSCP, Pharmacy Program Director, Accreditation Commission for Health Care (ACHC)
Brian Sapita, Director of Government Affairs, Michigan Pharmacists Association (MPA)

General Comment/Mollien - The General Rules need to be consistent with the Controlled Substances Rules. Any changes made to the Controlled Substances Rules should also be considered and appropriately updated in the General Rules for consistency.

Rule 338.501 Definitions.

Rule Numbers	Commenter	Comment
Section (1)	Mollien	"Written" is used throughout the rules without a definition. Add a definition making it clear that "written" allows for paper or electronic forms.
Rules Committee Response	The Rules Committee	

R 338.501 Definitions.
Rule 1. (1) As used in these rules:
(a) "Approved education program" means a school of pharmacy that is accredited by or has candidate status by the Accreditation Council for Pharmacy Education **(ACPE)**.
(b) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.
(c) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

(d) “Compounding” means the preparation, mixing, assembling, packaging, and labeling of a drug or device by a pharmacist under any of the following circumstances:

(i) Upon the receipt of a prescription for a specific patient.

(ii) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice.

(iii) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.

(iv) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

(e) "Compounding" does not include any of the following:

(i) Except as provided in section 17748c of the code, MCL 333.17748c, the compounding of a drug product that is essentially a copy of a commercially available product.

(ii) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.

(iii) The compounding of allergenic extracts or biologic products.

(iv) Flavoring agents added to conventionally manufactured and commercially available liquid medications. Flavoring agents must be nonallergenic and inert, not exceeding 5% of a drug product’s total volume.

(f) “Department” means the department of licensing and regulatory affairs.

(g) “Electronic signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by ~~a person~~ **an individual** with the intent to sign the record. An electronic signature is a unique identifier protected by appropriate security measures ~~such~~ that ~~it~~ is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.

(h) “Error prevention technology” means machinery and equipment used in a pharmacy setting to reduce dispensing medication errors including, but not limited to, barcode verification and radio frequency identification.

~~(h)~~ **(i)** “Manual signature” means a signature that is handwritten or computer-generated if a prescription is electronically transmitted as defined in section 17703~~(7)~~**(8)** of the code, MCL 333.17703~~(7)~~.

~~(i)~~ **(j)** “Practical experience” means professional and clinical instruction in, but not limited to, all of the following areas:

(i) Pharmacy administration and management.

(ii) Drug distribution, use, and control.

(iii) Legal requirements.

(iv) Providing health information services and advising patients.

(v) Pharmacist’s ethical and professional responsibilities.

(vi) Drug and product information.
(vii) Evaluating drug therapies and preventing or correcting drug-related issues.
~~(j)~~ **(k)** "Virtual manufacturer" means a person who engages in the manufacture of prescription drugs or devices and meets all of the following:
(i) Owns either of the following:
(A) The new prescription drug application or abbreviated new prescription drug application number.
(B) The unique device identification number, as available, for a prescription device.
(ii) Contracts with a contract manufacturing organization for the physical manufacture of the drugs or devices.
(iii) Is not involved in the physical manufacture of the drugs or devices.
(iv) At no time takes physical possession of or stores the drugs or devices.
(v) Sells or offers for sale to other persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.
(2) **Unless otherwise defined in these rules, the** ~~The~~ terms defined in the code have the same meaning when used in these rules.

Rule 338.505 Inspection of applicants and licensees.

Rule Numbers	Commenter	Comment
Section (2)	Sapita	Regarding R 338.505 subsection 2 which specifies "prelicensure inspection". Subsection 1 references both applicants and license holders but subsection 2 now excludes inspections of license holders. We suggest removing this language and keeping the original language.
Rules Committee Response	The Rules Committee	

R 338.505 Inspection of applicants and licensees.
Rule 5. (1) The board, board inspector, board agent, or ~~approved~~ **an** entity **approved** pursuant to R 338.532, may enter at reasonable times, any building, place, or facility that is owned or controlled by any applicant for, or holder of, a license to ~~make an inspection~~ **inspect** to enable the board to determine if the applicant possesses the qualifications and competence for the license sought or to determine whether a license holder is and has been complying with the code and rules. The inspection must concern only matters relevant to the applicant's or license holder's practice of pharmacy, manufacturing, and wholesale distributing of drugs and devices saleable by prescription only.
(2) ~~The~~ **A prelicensure** inspection must not extend to any of the following information:
(a) Financial data.

(b) Sales data other than shipment data.

(c) Pricing data.

(d) Personnel data other than data as to the qualifications of personnel performing functions subject to the acts and rules enforced by the board.

(e) Research data.

(3) An applicant or license holder shall permit and cooperate with the inspection.

Rule 338.523 Pharmacist license by endorsement; requirements.

Rule Numbers	Commenter	Comment
Section (ii)	Sapita	Regarding R 338.523 regarding Canadian pharmacists. Pharmacists throughout the state of Michigan are having a difficult time finding jobs in the current job market. We suggest removing subsection (ii).
Rules Committee Response	The Rules Committee	

R 338.523 Pharmacist license by endorsement; requirements.

Rule 23. (1) An applicant for licensure as a pharmacist by endorsement shall submit to the department a completed application on a form provided by the department with the requisite fee. An applicant who meets the requirements of this rule is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.

(2) An applicant shall satisfy all of the following requirements:

(a) Establish **1 of the following:**

(i) ~~that the he~~ **He** or she ~~is currently licensed~~ **holds a license in good standing as a pharmacist** in another state **and submits the NABP licensure transfer report to the department.**

~~or he or she successfully passed the foreign pharmacy graduate examination administered by NABP and was initially licensed by examination in another state.~~

(ii) He or she holds a pharmacy license in Canada that is in good standing and meets all of the following:

(A) He or she has passed the NAPLEX or both part I and part II of the Pharmacy Examining Board of Canada (PEBC) Pharmacists Qualifying Examination.

(B) He or she completed educational requirements for a pharmacist license from a school of pharmacy accredited by the ACPE or accredited by the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).

(C) If he or she held a pharmacist license for less than 1 year in Canada, he or she had acquired a minimum of 1,600 hours of pharmacy practice either through an approved internship or hours engaged in the practice as a pharmacist.

(b) Pass the MPJE as required under R 338.519.

(c) ~~Have his or her license verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.~~ **An applicant who is or has ever been licensed, registered, or certified in a health profession or specialty by any other state, the United States military, the federal government, or another country, shall do both of the following:**

(i) Disclose each license, registration, or certification on the application form.

(ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which include verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

~~(d) Submit the MPJE examination score report and NABP licensure transfer report to the department.~~

(d) He or she meets section 16174 of the code, MCL 333.16174, and submits his or her fingerprints to the department of state police to have a criminal background check conducted by the state police and the federal bureau of investigation.

(e) He or she completes a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(f) He or she completes a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

(g) He or she submits proof to the department of meeting the English language requirement under R 338.7002b and the implicit bias training required in R 338.7004.

(3) An applicant who has an FPGEC certification from NABP has met the English proficiency requirement. The applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.

Rule 338.531a Remote pharmacy waiver from mileage requirement.

Rule Numbers	Commenter	Comment
Section (2)(b)	Eid	Modify as follows: (b) A list **and explanation** of the services or availability of services that will be offered at the remote pharmacy that are different from the services offered at a pharmacy **or otherwise not readily available to patients** located within 10 miles of the proposed remote pharmacy. Comment: CVS Health supports the addition of language ensuring there is a route for remote

		pharmacies to obtain a waiver from milage requirements. This will increase access to care for patients and allow remote pharmacies that otherwise would not be allowed to exist, to provide services and patient care. Telepharmacy is nationally accepted by the National Association of Boards of Pharmacy (NABP), American Hospital Pharmacists Association (ASHP), and American Pharmacist Association (APhA) to create new or maintain current patient access to pharmacy services.1,2,3 While the milage restriction is contained in MI statute, it is recommended that the Department moves forward with language for a waiver from milage requirements. Many other states such as AZ, HI, ID, IL, ND, SD, UT, WV, and WI do not have milage restrictions.4,5,6 Studies have shown that pharmacy deserts exist in urban areas, amongst minority communities, and are not just limited to rural geographies.7 Using an evidenced based law-making philosophy showcases that studies have not shown that a milage restriction ensures an increase in patient safety or a decrease in patient harm. Add in the language above to strengthen the outcome of the rule is suggested. Rationale: Addition of "and explanation" to 2(b) will ensure the Department/Board has a clearer understanding of the services that will be offered rather than just a "list". It is observed that statement 2(c)(ii) would be optional since they only need to provide a statement of facts for one of more of what is listed in (i-iv). Addition of "or otherwise not readily available to patients" to 2(b) ensures the application is inclusive of services that may not be readily available to patients currently.
Section (2)(c)(i)	Sapita	MPA would like to urge the board to define what "limited access" actually means.
Section (2)(c)(ii)	Sapita	Given the ambiguity of the word "unique", how would the board verify that the service provided by a remote pharmacy is "unique".
Rules Committee Response	The Rules Committee	

R 338.531a Remote pharmacy waiver from mileage requirement.

Rule 31a. (1) An applicant seeking a remote pharmacy license may apply to the board for a waiver from the prohibition of locating a remote pharmacy within 10 miles of another pharmacy in section 17742a(2)(c) of the code, MCL 333.17742a, by submitting a completed application to the department, on a form provided by the department.

(2) The applicant shall submit the following with the application:

(a) A map showing the location of any existing pharmacies within 10 miles of the proposed remote pharmacy if the remote pharmacy will not be located at a hospital or mental health facility.

(b) A list of the services or availability of services that will be offered at the remote pharmacy that are different from the services offered at a pharmacy located within 10 miles of the proposed remote pharmacy.

(c) A statement of facts to support the statement of 1 or more of the following:

(i) The proposed remote pharmacy is located in an area where there is limited access to pharmacy services.

(ii) The proposed remote pharmacy will offer a service or the availability of a service that is unique from other pharmacies in the 10-mile radius from the remote pharmacy and the service will satisfy an unmet need of the surrounding community.

(iii) There exists a limitation on travel that justifies waiving the requirement.

(iv) There are other compelling circumstances that justify waiving the requirement.

(3) If the waiver is denied, the application is considered closed unless within 30 days of receipt of the denial, the applicant notifies the department that it is requesting a hearing on the matter.

Rule 338.534 Inspections.

Rule Numbers	Commenter	Comment
Section (3)	Pritchett	We have learned over the course of this year that R 338.534 was modified to require all applicants for licensure as a sterile compounding pharmacy to have a physical inspection **and** corresponding report completed within 18 months of application. In previous years, the pharmacy was required to submit evidence of current accreditation ***or*** an inspection report completed within 18 months of application. My understanding is that this was originally put together as an either/or option because procedural differences by which the various inspection and accreditation bodies operate. Requiring an inspection within 18 months of application presents a problem with the previously-approved PCAB process. Accreditations with ACHC are provided on a 36-month cycle, which aligns with accreditation programs provided in other areas of the healthcare industry as well as requirements issued by the Centers for Medicare and Medicaid Services (CMS). A survey occurs prior to each new accreditation cycle, thus a survey roughly every 36 months. This creates a mis-alignment with the Michigan licensure schedule of renewal every 2 years; some pharmacies,

		depending on where they are in their accreditation cycle, will not be scheduled for a survey within the 18 months preceding renewal of their licensure. In addition this this challenge, COVID-19 has created an additional burden. Early in 2021 accreditation organizations were permitted to perform remote surveys in lieu of on-site surveys, of which PCAB did many. The current requirement is that a "physical" inspection is to have occurred, so a strict reading of the rule would mean that the board-permitted virtual survey would not be compliant with the rule. Currently, PCAB accredits approximately 100 pharmacies for sterile compounding in Michigan. Nearly 30 were surveyed with an approved virtual survey in 2021, so the question remains as to whether or not that will satisfy the licensure requirement for renewal. Of the remaining pharmacies, approximately ½ of them would require some sort of off-cycle survey in order to meet the licensure window, which presents a considerable unexpected financial strain on the pharmacy as well as a resource burden on ACHC. ACHC requests that the rule be returned to requiring **either** evidence on a current accreditation **or** a physical inspection and corresponding report completed within 18 months of application. We would also like to see clarification about acceptance of the use of virtual surveys during a public health emergency, as the issues surrounding COVID-19 appear to be ongoing.
Rules Committee Response	The Rules Committee	

R 338.534 Inspections.

Rule 34. (1) A pharmacy located outside of this state that applies for licensure in this state as a pharmacy that will not ship compounded sterile pharmaceutical products into this state~~,~~ shall submit to the department a copy of its most recent pharmacy inspection that was performed within the last 2 years **from the date of application**.

(2) An applicant for a new pharmacy located in this state shall have an inspection conducted by the department or its designee prior to licensure.

(3) An applicant for licensure **or renewal** of ~~a~~ **an in-state or out-of-state** pharmacy that will provide sterile compounded pharmaceuticals **in this state** shall have ~~all of the following:~~

~~(a) An~~ **an** onsite physical inspection **and submit a physical inspection report to the department, completed no more than 18 months before the date of application, that demonstrates compliance with all applicable standards that are adopted by reference in R 338.533. The inspection must be** conducted by ~~any~~ **1** of the following:

~~(i)~~**(a)** The department.

~~(ii)~~**(b)** The ~~national association of boards of pharmacy verified pharmacy program~~ **NABP-Verified Pharmacy Program** (NABP-VPP).

~~(iii)~~**(c)** An accrediting organization according to R 338.532.

~~(iv)~~**(d)** A state licensing agency of the state in which the applicant is a resident and in accordance with the NABP's multistate pharmacy inspection blueprint program.

~~(b) A physical inspection and corresponding report completed within 18 months of application.~~

~~(c) A physical inspection and corresponding report that demonstrates compliance with all applicable standards that are adopted by reference in R 338.533.~~

~~(4) An out-of-state pharmacy that intends to ship sterile compounded pharmaceutical products into this state shall obtain an inspection from a board approved accrediting organization every 18 months.~~

Rule 338.561 Pharmacy as wholesale distributor; licensure.

Rule Numbers	Commenter	Comment
Sections (a) to (d)	Mollien	Do not delete these exemptions. These exemptions remain applicable under 21 USC 353(e)(4).
Rules Committee Response	The Rules Committee	

R 338.561 Pharmacy as wholesale distributor; licensure.

Rule 61. ~~A pharmacy that transfers prescription drugs or devices shall obtain a wholesale distributor license if it distributes more than 5% of the total dosage units of prescription drugs dispensed during any consecutive 12-month period, except in the following circumstances:~~

A pharmacy shall obtain a license as a wholesale distributor under this part if the total number of dosage units of all prescription drugs distributed by the pharmacy to a person during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the same 12-month period. The calculation of this 5% threshold must not include a distribution of a prescription drug that is exempt from the definition of wholesale distribution under 21 USC 353(e)(4).

~~(a) The distribution of a drug among hospitals or other health care entities which are under common control.~~
~~(b) Intracompany distribution of any drug between members of an affiliate, defined pursuant to section 360eee(1) of the Federal Food, Drug, and Cosmetic Act, 21 USC section 360eee(1), or within a manufacturer.~~
~~(c) Distribution of a drug by a charitable organization to a nonprofit affiliate of the organization, defined pursuant to section 360eee(1) of the Federal Food, Drug, and Cosmetic Act, 21 USC section 360eee(1).~~
~~(d) Distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, 42 USC 247d.~~

Rule 338.563 Wholesale distributor; wholesale distributor-broker; application for licensure; requirements.

Rule Numbers	Commenter	Comment
Section (2)(h)	Mollien	Clarify if this FDA certification requirement is necessary and if it is necessary whether it should only apply to distributions of blood and blood products.
Rules Committee Response	The Rules Committee	

R 338.563 Wholesale distributor**, wholesale distributor-broker**; application for licensure; requirements.

Rule 63. (1) An applicant for a wholesale distributor **or wholesale distributor-broker** license shall submit to the department a completed application on a form provided by the department with the requisite fee. A wholesale distributor includes virtual manufacturers.

(2) An applicant shall **comply with** ~~provide~~ all of the following ~~information~~:

(a) **Provide** ~~A~~ **a** criminal history background check required pursuant to section 17748(6) of the code, MCL 333.17748~~(6)~~.

(b) ~~Proof of registration or licensure from every state where the applicant currently holds or has ever held a license or registration.~~ **Disclose on the application form each license, registration, or certification in a health profession or specialty issued by any other state, the United States military, the federal government, or another country.**

(c) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which include verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

~~(c)~~**(d) Provide** ~~Certified~~ **certified** copies of articles of incorporation or certificates of partnership and assumed names if applicable.

~~(d)~~ **(e) Provide** ~~The~~ **the** identity and address of each partner, officer, or owner as applicable.

~~(e)~~**(f) Provide a** ~~A~~ completed compliance checklist.

~~(f)~~**(g) Provide a FEIN certificate.** ~~list or catalog of all drug products and devices to be distributed.~~

~~(g)~~**(h) Provide a** copy of the FDA certification for the site to be licensed, if the applicant is distributing biologicals.

~~(h)~~**(i)** Unless exempt under section 17748(2) of the code, MCL 333.17748~~(2)~~, **provide** the name and the license number of the pharmacist designated as the ~~pharmacist in charge (~~PIC~~)~~ or the name of the facility manager. For individuals designated as a facility manager, the applicant shall provide ~~the following:~~

~~(i) Proof~~**proof**, in the form of an affidavit, that the facility manager has achieved the following:

(~~A~~**i**) A high school equivalency education, or higher, defined as 1 of the following:

(~~I~~**A**) A high school diploma.

(~~II~~**B**) A ~~general education development certificate (~~GED~~)~~.

(~~III~~**C**) A parent-issued diploma for home schooled individuals.

(~~IV~~**D**) Completion of post-secondary education, including an associate's, bachelor's, or master's degree.

(~~B~~**ii**) Completion of a training program that includes, but is not limited to, all of the following subjects:

(~~I~~**A**) Knowledge and understanding of laws in this state and federal laws relating to the distribution of drugs and devices.

(~~II~~**B**) Knowledge and understanding of laws in this state and federal laws relating to the distribution of controlled substances.

(~~III~~**C**) Knowledge and understanding of quality control systems.

(~~IV~~**D**) Knowledge and understanding of the USP standards relating to the safe storage and handling of prescription drugs.

(~~V~~**E**) Knowledge and understanding of pharmaceutical terminology, abbreviations, dosages, and format.

(~~C~~**iii**) Experience equal to either of the following:

(~~I~~**A**) A minimum of 1 year of work experience related to the distribution or dispensing of prescription drugs or devices where the responsibilities included, but were not limited to, recordkeeping.

(~~II~~**B**) Previous or current employment as a designated representative of a wholesale distributor certified by the VAWD of NABP **or of a wholesale distributor-broker**.

(iv) Current employment with the applicant.

(j) Provide a list or catalog of all drug products and devices to be distributed, if a wholesale distributor.

(k) Submit an affidavit, at the time of the application for initial licensure, that the applicant facilitates deliveries or trades for at least 50 qualified pharmacies and that each pharmacy holds a license in good standing as a pharmacy from the state in which it is located at the time of application, if a wholesale distributor-broker.

(3) A wholesale distributor or wholesale distributor-broker that changes its facility manager shall submit all of the information required in subrule (2)(i) of this rule to the department within 30 days of the change.

Rule 338.569 Wholesale distributor and wholesale distributor-broker recordkeeping and policy requirements.

Rule Numbers	Commenter	Comment
Section (4)	Mollien	These rules create a significant public health and safety gap that allows introduction of counterfeit medications into the closed distribution supply chain. To close this gap, clarify in this ruleset that any purchasing pharmacy using a wholesale distributor-broker to facilitate a transaction from a pharmacy not licensed in Michigan shall request the transaction history, transaction statement or transaction information for the drugs supplied.
Section (6)	Mollien	Change to department, board, and …
Rules Committee Response	The Rules Committee	

R 338.569 Wholesale distributor **and wholesale distributor-broker** recordkeeping and policy requirements.

Rule 69. (1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt, if applicable, and the distribution or other disposition of prescription drugs or devices. These records must include all of the following information:

(a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped.

(b) The identity and quantity of the prescription drugs or devices received, if applicable, and distributed or disposed of.

(c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.

(2) A wholesale distributor shall establish and maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(3) A wholesale distributor shall have written policies and procedures that include all of the following:

(a) A procedure whereby the oldest stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(b) A procedure for handling recalls and withdrawals of the prescription drugs or devices. The procedure must deal with recalls and withdrawals due to any of the following:

(i) Any action initiated at the request of the FDA~~,~~**;** other federal**,** state**,** or local law enforcement agency~~,~~**;** or other governmental agency.

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective prescription drugs or devices from the market.

(iii) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c) A procedure to ensure that a wholesale distributor prepares for, protects against, and handles, any crises that affects security or operation of any facility in the event of employee strike, flood, fire, or other natural disaster, or other local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs or devices will be segregated from other prescription drugs or devices and either returned to the manufacturer or destroyed. This procedure must include a provision for the written documentation of the disposition of outdated prescription drugs or devices that must be maintained for 2 years after the disposition of the outdated prescription drugs or devices.

(e) Procedures for identifying, recording, and reporting losses or thefts of prescription drugs or devices and for correcting errors and inaccuracies in inventory.

(4) A wholesale distributor-broker shall establish and maintain a list of officers, directors, managers, and other persons who are in charge of wholesale drug delivery and trade, including a description of their duties and a summary of their qualifications.

(5) A wholesale distributor-broker shall maintain for at least 7 years the transaction history, transaction statements, and transaction information required by section 17748e of the code, MCL 333.17748e.

~~(4)~~**(6)** The records described in subrules (1) ~~and (2)~~ **to (5)** of this rule **and section of 17748e of the code, MCL 333.17748e,** must be made available for inspection and photocopying by **the department and** authorized federal, state, or local law enforcement agency officials. The records that are kept on-site or that are immediately retrievable by computer or other electronic means must be readily available for an authorized inspection during the retention period described in ~~subrule (5)~~**subrules (5) and (7)** of this rule. Records that are kept at a central location apart from the site must be made available for inspection within 2 working days of a request.

~~(5)~~**(7) A wholesale distributor shall retain the**~~The~~ records described in this rule ~~must be maintained~~ for a minimum of 2 years after the disposition of the prescription drugs or devices.

Rule 338.584 Noncontrolled prescriptions.

Rule Numbers	Commenter	Comment
Section (1)(g)	Baran	Change 338.584(1)(g) to "Issue date of the prescription." The prescriber will not know the date the prescription was dispensed when issuing a prescription.
Section (1)(g)	Novak	Under subrule (1), MSMS recommends that subrule (1)(g) be deleted. A prescriber does not know, at the time he or she is issuing a prescription, the date that it will be dispensed by a pharmacist. MSMS believes this language was added in error to Rule 84 or is intended to address another issue

		for which clarifying language is necessary.
Rules Committee Response	The Rules Committee	

R 338.584 Noncontrolled prescriptions.

Rule 84. (1) A prescriber who issues a prescription for a noncontrolled prescription drug shall date the prescription; provide a manual signature on the prescription~~, as defined in R 338.501(1)(h) of these rules~~; and ensure that the prescription contains all of the following information:

(a) The full name of the patient for whom the drug is being prescribed.

(b) The prescriber's **preprinted, stamped, typed, or manually** printed name and address.

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

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

(g) The date the prescription was dispensed.

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

(2) A prescriber shall ensure that a prescription is legible and that the information specified in subrule (1)(c) to ~~(f)~~**(h)** of this rule is clearly separated.

(3) A prescriber shall not prescribe more than either of the following on a single prescription form as applicable:

(a) For a prescription prescribed in handwritten form, up to 4 prescription drug orders.

(b) For a prescription prescribed on a computer-generated form or a preprinted list or produced on a personal computer or typewriter, up to 6 prescription drug orders.

(4) A prescription is valid for 1 year from the date the prescription was issued.

~~(5) A prescriber may electronically transmit a noncontrolled substance prescription to the pharmacy of the patient's choice by utilizing a system that includes all of the following:~~

~~(a) A combination of technical security measures such as, but not limited to, those listed in security standards for the protection of electronic protected health information set forth in 45 CFR 164.312 (2013) that implements the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), to ensure all of the following:~~

~~(i) Authentication of an individual who prescribes or dispenses.~~

~~(ii) Technical non-repudiation.~~

~~(iii) Content integrity.~~

~~(iv) Confidentiality.~~
~~(b) An electronic signature as defined in R 338.501(1)(g). An electronic signature is valid when it is used to sign a noncontrolled prescription.~~
~~(c) Appropriate security measures to invalidate a prescription if either the electronic signature or prescription record to which it is attached or logically associated is altered or compromised following transmission by the prescriber. The electronic prescription may be reformatted to comply with industry standards provided that no data is added, deleted, or changed.~~
~~(6) The electronic prescription must meet all requirements of the HIPAA.~~
~~(7) The electronic prescription must permit the prescriber to instruct the pharmacist to dispense a brand name drug product provided that the prescription includes both of the following:~~
~~(i) The indication that no substitute is allowed, such as "dispense as written" or "DAW."~~
~~(ii) The indication that no substitute is allowed and that it is a unique element in the prescription.~~
~~(8) If the prescription is transmitted electronically, the prescriber shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form. The electronic prescription must identify the name of the pharmacy intended to receive the transmission, and must include the information identified in subrule (1) of this rule.~~
~~(9) The electronic prescription must be preserved by a licensee or dispensing prescriber for not less than 5 years. A paper version of the electronic prescription must be made available to an authorized agent of the board upon request. A secured copy must be retained for a minimum of 1 year by the transaction service vendor for record-keeping purposes and must be shared only with the parties involved in the transaction except as otherwise permitted by state or federal law.~~
~~(10) An electronic signature that meets the requirements of this rule has the full force and effect of a handwritten signature on a paper-based written prescription.~~
~~(11)~~ **(5)** A pharmacy shall keep the original prescription record for 5 years. After ~~3~~ **2** years **from the date of the prescription's issue date**, a pharmacy may make an electronic duplicate of the original **non-controlled** paper prescription, which ~~will become~~**becomes** the original prescription. A pharmacy shall present a paper copy of the electronic duplicate of the prescription to an authorized agent of the board upon request.
~~(12)~~ **(6)** This rule does not apply to pharmacy services provided in a medical institution.

Rule 338.584a Electronic transmission of prescription; waiver of electronic transmission.

Rule Numbers	Commenter	Comment
Section (1)	Novak	Under subrule (1), MSMS recommends that the date be consistent with the effective date in the statute and that there be consistency on this issue between Rule Set 2020-128 LR and Rule Set 2020-82 LR.

		(1) Until 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,…
Section (1)	Mollien	Align with controlled substances ruleset. Consider, "Until the enforcement date established by…".
Section (3)	Novak	MSMS requests the language in subrule (3) be amended to recognize the exceptions to electronic transmissions permitted by MCL §333.17754a, as follows: (3) 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 (3)	Mollien	Conform with Rule 84(1).
Section (4)(b)(iv)	Novak	MSMS also recommends subrule (4)(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 per year. B. Intention to cease practice within the next twelve months. C. Limited practice due to an illness or other unforeseen event.
Rules Committee Response	The Rules Committee	

R 338.584a Electronic transmission of prescription; waiver of electronic transmission.

Rule 84a. (1) Until January 1, 2022, or the 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 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 as 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 338.584.

(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 January 1, 2022, or the date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement, whichever occurs later, prescribers shall electronically transmit a prescription 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 338.584 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 shall satisfy all of the following requirements:

(a) The prescriber is unable to meet the requirements of section 17754a(1) 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 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.

(5) 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 338.587 Prescription refill records; manual systems; profile systems; automated pharmacy data systems; nonapplicability to medical institution service; record confidentiality; and access.

Rule Numbers	Commenter	Comment
Section (4)(e)	Sapita	We believe the use of "on site" is confusing since after 2 years the prescription information can be kept electronically. We suggest that "on site" be removed from this subsection entirely.
Rules Committee Response	The Rules Committee	

R 338.587 Prescription refill records; manual systems; profile systems; automated pharmacy data systems; nonapplicability to medical institution service; record confidentiality; and access.

Rule 87. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.

(2) A pharmacy may utilize a manual system of recording refills if the system ~~is in compliance~~ **complies** with both of the following criteria:

(a) The amount and date dispensed must be entered on the prescription in an orderly fashion and the dispensing pharmacist initials the entry. If the pharmacist only initials and dates the prescription, then the full face amount of the prescription must be deemed dispensed.

(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated on the prescription.

(3) A pharmacy may utilize a uniform system of recording refills if the system ~~is in compliance~~ **complies** with all of the following criteria:

(a) Records must be created and maintained in written form. All original and refill prescription information for a particular prescription appears on single documents in an organized format. ~~The pharmacy shall preserve the records for 5 years.~~ The records are subject to inspection by the board or its agents.

(b) The following information for each prescription must be entered on the record:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal drug enforcement administration (DEA) number, if appropriate.

(v) The number of refills authorized.

(vi) The "dispense as written" instructions, if indicated.
(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed, and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.
(viii) The date of issuance of the prescription.
(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill. **If a pharmacy technician performs final product verification, the identification of the delegating pharmacist and pharmacy technician must be recorded.**

(c) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled.

(d) The information required by subdivision (b) of this subrule must be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.

(4) A pharmacy may utilize a uniform automated data processing system of recording refills if the system ~~is in compliance~~ **complies** with all of the following criteria:

(a) All information that is pertinent to a prescription must be entered on the record, including all of the following information:
(i) The prescription number.
(ii) The patient's name and address.
(iii) The prescriber's name.
(iv) The prescriber's federal DEA number, if appropriate.
(v) The number of refills authorized.
(vi) Whether the drug must be dispensed as written.
(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.
(viii) The date of issuance of the prescription.
(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill. **If a pharmacy technician performs final product verification, the identification of the delegating pharmacist and pharmacy technician must be recorded.**

(b) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. ~~The pharmacy shall preserve the records on-site for 5 years.~~ **A pharmacy shall keep the original prescription record on site for 5 years. After 2 years from the date of the prescription's issue date, a pharmacy may make an electronic duplicate of the original non-controlled paper prescription, which will become the original prescription.** The records are subject to inspection by the board or its agents. A procedure must be established to facilitate inspections.

(c) The required information must be entered on the record for all prescriptions filled at the pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.586.

(d) The recording system must provide adequate safeguards against improper manipulation, the alteration of records, and the loss of records.

(e) The recording system must have the capability of producing a printout of all original and refilled prescription data, including a prescription-by-prescription and refill-by-refill audit trial for any specified strength and dosage form of a controlled substance by either brand or generic name or an audit trail of controlled substance prescriptions written for a particular patient or by a particular practitioner. A printout of an audit trail or other required information must be made available to an authorized agent of the board upon request. The prescription data must be maintained **on site** for 5 years. Data older than ~~16 months~~ **2 years** must be provided within 72 hours of the time the request is first made by the agent. Prescription data for the most current ~~16 months~~ **2 years** must be readily retrievable on site and available for immediate review.

(f) If the automated data processing system is inoperative for any reason, then the pharmacist shall ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist shall enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours.

(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to ensure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall ensure continuity in the maintenance of records.

(h) The automated data processing system must be an integrated system that is capable of complying with all of the requirements of these rules.

(5) This rule does not apply to pharmacy services provided in a medical institution.

(6) Records that are created under subrule (2), (3) or (4) of this rule are subject to the same requirements regarding confidentiality and access that apply to original prescriptions.

Rule 338.588 Automated devices.

Rule Numbers	Commenter	Comment
Section (3)	Eid	Modify to: (3) A pharmacy that operates an automated device under this section to deliver a drug or device directly to an ultimate user or health care provider shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist. **A secured, lockable, and privacy enabled automated device located on the premise of the licensed pharmacy may be utilized as a means for patient's or an agent of the patient to pick up prescription medications when and if a pharmacy is closed.** Rationale: As technology continues to advance ensuring that patients can safely and securely pick up their medications from a pharmacy is a priority. Patients at times may not be able to get to a pharmacy to pick up or may have medications such as antibiotics or other emergent situations they need to obtain, but their pharmacy may be closed. Ensuring automated devices which are secured, locked, and guarantee privacy could expand access to care after hours or during lunch breaks/other closures and ensure patients have a route which is trustworthy to obtain their medications. Yeo et al. is a recent study which showcased the benefits of allowing such operational models.1 Other states such as AZ, CA, CT, DE, DC, FL, ID, IL, IN, IA, LA, ME, MD, MA, MO, MT, NV, OR, PA, RI, SC, SD, TX, WA, WV, and WY allow for such practices within their laws/rules.2,3,4 Add in clarifying language to allow for use of automated devices as patient pick-up options within the premises of a licensed pharmacy is recommended.
Rules Committee Response	The Rules Committee	

R 338.588 Automated devices.

Rule 88. (1) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction information.

(2) An automated device may be used only in the following locations:

(a) A pharmacy, or at the same physical address as the pharmacy provided that the location of the automated device is owned and operated by the same legal entity as the pharmacy.

(b) A hospital.

(c) A county medical care facility.

(d) A hospice.

(e) A nursing home.

(f) Other skilled nursing facility as defined in section 20109(4) of the code, MCL 333.20109~~(4)~~.

(g) An office of a dispensing prescriber.

(h) A location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, consistent with section 17760 of the code, MCL 333.17760.

(3) A pharmacy that operates an automated device under this section to deliver a drug or device directly to an ultimate user or health care provider shall notify the department of the automated device's location on a form provided by the department. An automated device located within a licensed pharmacy must be used only by a pharmacist or his or her pharmacy personnel under the personal charge of a pharmacist.

(4) If an automated device is used in a dispensing prescriber's office, the device must be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. A pharmacy shall not own, control, or operate an automatic dispensing device in a dispensing prescriber's office, unless the prescriber's office is affiliated with a hospital consistent with section 17760 of the code, MCL 333.17760**,** and subrule (2)(h) of this rule. All of the following apply to the use of an automated device in a dispensing prescriber's office:

(a) If a dispensing prescriber 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 a board-approved error prevention technology that complies with R 338.3154.

(b) A dispensing prescriber operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(c) If any medication or device is dispensed from an automated device in a dispensing prescriber's office, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the dispensing prescriber for review by an agent of the board. This documentation must include at least all of the following information:

(i) Manufacturer name and model.

(ii) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(iii) Policy and procedures for system operation that addresses**,** at a minimum**,** all of the following:

(A) Accuracy.

(B) Patient confidentiality.
(C) Access.
(D) Data retention or archival records.
(E) Downtime procedures.
(F) Emergency procedures.
(G) Medication security.
(H) Quality assurance.

(5) An automated device that is to be used for furnishing medications for administration to registered patients in any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in section 20109(4) of the code, MCL 333.20109~~(4)~~, must be supplied and controlled by a pharmacy that is licensed in this state. The use of an automated device in these locations is not limited to the provisions of subrule (3) of this rule. If a pharmacist delegates the stocking of the 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 board-approved error-prevention technology. Each automated device must comply with all of the following provisions:

(a) A pharmacy operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(b) If 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 must be maintained by the pharmacy for review by an agent of the board. The documentation must include at least all of the following information:

(i) Name and address of the pharmacy responsible for the operation of the automated device.
(ii) Name and address of the facility where the automated device is located.
(iii) Manufacturer name and model number.
(iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.
(v) Policy and procedures for system operation that address**,** at a minimum**,** all of the following:
(A) Accuracy.
(B) Patient confidentiality.
(C) Access.
(D) Data retention or archival records.
(E) Downtime procedures.
(F) Emergency procedures.
(G) Medication security.

(H) Quality assurance.
(I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.

(6) An automated device that is operated at a location affiliated with a hospital, but not at the same physical address as the pharmacy, that is owned and operated by the hospital, must comply with section 17760 of the code, MCL 333.17760.

(7) Records and electronic data kept by automated devices must meet all of the following requirements:

(a) All events involving access to the contents of the automated devices must be recorded electronically.

(b) Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:
(i) The unique identifier of the automated device accessed.
(ii) Identification of the individual accessing the automated device.
(iii) The type of transaction.
(iv) The name, strength, dosage form, quantity, and name of the manufacturer of the drug accessed.
(v) The name of the patient for whom the drug was ordered.
(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.

(8) Policy and procedures for the use of the automated device must 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)(j).

(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**.**

(e) The automated device is located in a dispensing prescriber's office.

(9) A copy of all policies and procedures related to the use of an automated device must be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

New Rule **Pharmacy acquisition and distribution records.**

Rule Numbers	Commenter	Comment
	Mollien	The rules are missing the record retention requirements applicable to pharmacies related to non-control drug and device acquisition and distribution records. ADD R 338.589 Pharmacy Acquisition and Distribution Records Rule 59. (1) A pharmacy must keep and make available for inspection all acquisition and distribution records for prescription and non-prescription drugs and devices, such as invoices, packing slips or receipts, for 5 years. All records, which may be electronic, must be readily retrievable within 48 hours. (2) Acquisition and distribution records must include the following information: (a) The source of the prescription drugs or devices, including the name and principal address of the seller or transferor and the address from which the prescription drugs or devices were shipped. (b) The identity and quantity of the prescription drugs or devices received, if applicable, and distributed or disposed of. (c) The dates of receipt, if applicable, and distribution of the prescription drugs or devices.
Rules Committee Response	The Rules Committee	