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

Testimony/Comments Received:

Rose M. Baran, PharmD
Kendra Croker, Manager, Regulatory Affairs, Telepharm
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 agrees with the comment to add a definition of "written" to clarify that it allows for paper or electronic forms.	

Board Response	The Board agrees with the comment that the term "written" should be added to the definitions with clarification that the term allows for paper or electronic forms.

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.

(l) "Written" includes both paper and electronic forms.

(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 agrees with the comment that clarification is needed. The Rules Committee recommends modifying (2) to "Inspections in provision (1) must not extend to any of the following information, however, the information is subject to a disciplinary investigation."	

Board Response	The Board agrees with the comment that provision (1) and (2) are inconsistent with the addition of "prelicensure" in (2) and, therefore, "prelicensure should be deleted, and additional language should be added to (2), "Inspections in provision (1) must not extend to any of the following information, however, the information

	is subject to a disciplinary investigation.”

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~~ **inspections in provision (1)** must not extend to any of the following information**, however, the following information is subject to a disciplinary investigation**:

(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 (2)(a)(ii)	Sapita	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 declines the comment as endorsement of Canadian licensees is authorized by the Public Health Code.	

Board Response	The Board declines the comment as endorsement of Canadian licensees is authorized and required by the Public Health Code.

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)(a)	Croker	Delete the requirement of a map as it is already requested with the application for the remote pharmacy.
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)(i) and (ii)	Croker	Delete (i) and (ii).
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	Section (2)(b) Eid - The Rules Committee agrees with the comment to modify (b) as follows: "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." Sections (2)(c)(i) and (ii) Sapita – The Rules Committee declines to define "limited access" or "unique" to avoid unintentionally limiting those who may qualify for a waiver. Section (2)(a) Croker – The Rules Committee declines to delete the requirement of a map as it is needed with the application for the waiver. Section (2)(c)(i) and (ii) Croker - The Rules Committee declines to delete (i) and (ii) as they allow for additional reasons for a waiver and the Rules Committee does not want to further limit an applicant's ability to request a waiver.	

Board Response	Section (2)(b) - The Board agrees with the comment to modify (b) as follows: "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." Sections (2)(c)(ii) and (ii) – The Board declines to define "limited access" or "unique" to avoid unintentionally limiting those who may qualify for a waiver. Section (2)(a) – The Board declines to delete the requirement of a map as it is needed with the application for the waiver. Section (2)(c)(i) and (ii) - The Board declines to delete (i) and (ii) as they allow for additional reasons for a

	waiver and the Board does not want to further limit an applicant's ability to request a waiver.

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 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.

(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 misalignment 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 agrees with the comment that the rule should be modified to allow for virtual inspections if the inspection entity determines that it is the best option at the time but declines the suggestion to increase the time between inspections to 36 months as the Rules Committee believes allowing more time between inspections is not in the best interest of the public.	

Board Response	The Board agrees that virtual inspections should be acceptable as the board approves the entities that provide the inspections and can refuse to renew their status as board approved if they do not provide thorough inspections. Further, the Board agrees that a pharmacy that has been accredited should not have to submit an inspection within 18 months before the date of an application. The Board will add the following language to (3) "unless accredited by a national accrediting organization, recognized by the board, an … ."

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~~ **Unless accredited by a national accrediting organization, recognized by the board, 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~~ **the 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 declines the comment to keep (a) through (d) as they are already included in the definition of "wholesale distribution" under 21 USC 353(e)(4).	

Board Response	The Board declines the comment to keep (a) through (d) as they are already included in the definition of "wholesale distribution" under 21 USC 353(e)(4).

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 agrees that (h) should be deleted as there is no FDA certification for a wholesale distributor who is distributing biologicals.

Board Response	The Board declines the comment to delete (h) and will add "if required by the FDA" to the rule.

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**, if a certification is required by the FDA,** 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	Section (4) and (6) - The Rules Committee agrees with the comment that a purchasing pharmacy that is using a broker to facilitate the transaction from a pharmacy that is not licensed in Michigan should request the transaction history, transaction statement, or transaction information for the drugs supplied, and board" should be added to (6).

Board Response	The Board agrees with the comment that a purchasing pharmacy that is using a broker to facilitate the transaction from a pharmacy that is not licensed in Michigan should request the transaction history, transaction statement, or transaction information for the drugs supplied. The Board also agrees that "board" should be added to (6).

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), and (8)** of this rule **and section of 17748e of the code, MCL 333.17748e,** must be made available for inspection and photocopying by **the department, board, 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.

(8) A purchasing pharmacy using a wholesale distributor-broker to facilitate a transaction from a pharmacy that is not licensed in Michigan shall request the transaction history, transaction statement or transaction information for the drugs supplied.

New Rule 583a 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 Pharmacy Acquisition and Distribution Records (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 agrees with the comment that a rule regarding pharmacy acquisition and distribution records should be added.	

Board Response	The Board agrees with the comment that for consistency with the controlled substances rules, a rule regarding pharmacy acquisition and distribution records should be added.

R 338.583a Pharmacy acquisition and distribution records.

Rule 83a. (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.

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 agrees with the comments and recommends "dispensed" be modified to "issued."	

Board Response	The Board agrees with the comment to replace "dispensed" with "issued."

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~~ issued.

(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	Section (1) and (3) 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.	

	Section (3) – 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. Section (4)(b)(iv) – The Rules Committee agrees with most of the clarifying language regarding "exceptional circumstances." The Rules Committee agrees with adding (B) and (C), however, would suggest deleting (A) as this basis is really a claim for economic hardship, which is already in the rule. The Rules Committee agrees with the comment to clarify that an attestation will be used to show exceptional circumstances. For consistency with the Controlled Substances rules and Code, the following are recommended: • As the Code requires that if a CMS waiver is granted then the Department shall grant a waiver, provision (4) should be modified to allow for this waiver without meeting other requirements. Therefore, (4) will be reorganized. • 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. "This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions."

Board Response	The Board agrees with the following: Section (1) and (3) 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. Section (3) – The rules should be amended to recognize the exceptions to electronic transmissions permitted by MCL §333.17754a. Section (4)(b)(iv) – The clarifying language regarding "exceptional circumstances" will be added. The Board agrees with

	adding (B) and (C), however, would suggest deleting (A) as this basis is really a claim for economic hardship, which is already in the rule. The comment to clarify that an attestation will be used to show exceptional circumstances will be added to (4)(b)(iv). As the Code requires that if a CMS waiver is granted then the Department shall grant a waiver, provision (4) should be modified to allow for this waiver without meeting other requirements. Therefore, (4) will be reorganized. 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. "This rule does not apply to the use of electronic equipment to transmit prescription orders within inpatient medical institutions."

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

Rule 84a. (1) Until ~~January 1, 2022, 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 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~~ on the enforcement 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 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 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) 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 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) Intention to cease practice within the next twelve months.

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

(iv) 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 agrees to delete "on site" in (e).	

Board Response	The Board agrees to delete "on site" in (e).

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~~ **trail** 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 agrees with the comment as it clarifies that a pharmacy may use an automated device within the pharmacy. The Rules Committee recommends changing the language by deleting "and if a pharmacy is closed." In addition, for clarity with the addition of this language, add "only", non-controlled, and modify "used" to "under control."	

Board Response	The Board agrees with the comment as it clarifies that a pharmacy may use an automated device within the pharmacy. The Rules Committee recommends changing the language by deleting "and if a pharmacy is closed." In addition, for clarity with the addition of this language, add "only", non-controlled, and modify "used" to "under control."

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 **only** to deliver a **non-controlled** 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~~ **under the control** ~~only by~~ **of** 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 a patient or an agent of the patient to pick up prescription medications.**

(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.

MICHIGAN PHARMACISTS ASSOCIATION

September 21, 2021

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing
Boards and Committees Section
PO Box 30670
Lansing, MI 48909-8170

Dear Policy Analyst,

The Michigan Pharmacists Association (MPA) would like to thank the Michigan Board of Pharmacy within the Michigan Department of Licensing and Regulatory Affairs for allowing us to submit our comments on the proposed administrative rules 2020-128 LR, Pharmacy – General Rules governing the rules for pharmacy professionals. MPA represents pharmacists, pharmacy technicians, and student pharmacists across the state. We are strong proponents of offering increased access to care to all Michiganders in a safe and effective way. We would like to take this opportunity to changes to these rules.

1. 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.
2. 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).
3. Regarding R 338.531a
    a. subsection 2(c)(i) which specifies "limited access to pharmacy services". MPA would like to urge the board to define what "limited access" actually means.
    b. Subsection 2(c)(ii) which specifies "service that is unique from other pharmacies…". Given the ambiguity of the word "unique", how would the board verify that the service provided by a remote pharmacy is "unique".
4. Regarding R 338.586 subsection 4(e). which specifies "on site". 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.

Again, the Michigan Pharmacists Association would like to thank you for taking the time to review our concerns. If you have any additional questions, I can be reached at the information below.

Sincerely,

Brian Sapita
Director of Government Affairs
Ph: 517-377-0254
Email: Brian@MichiganPharmacists.org

From: Jon Pritchett Pharm.D., RPh., BCSCP
To: Ditschman, Andria (LARA)
Subject: Board of Pharmacy - comments of rules revision - R 338.534
Date: Friday, September 17, 2021 4:50:09 PM
Attachments: image002.png
image003.png
image004.png
image005.png
image006.png

Hello,

I am the Pharmacy Program Director with Accreditation Commission for Health Care (ACHC), which provides sterile compounding accreditation through the Pharmacy Compounding Accreditation Board (PCAB) nationally and internationally, and is approved in the state of Michigan as an accreditation/inspection entity for the purpose of assessing compliance with USP standards (see https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_27529_27548_91200-366832--,00.html).

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. The following excerpt was provided to ACHC by several Michiganlicensed
pharmacies:

3) An applicant for licensure of a pharmacy that will provide sterile compounded pharmaceuticals shall have all of the following:
(a) An onsite physical inspection conducted by any of the following:
(i) The department.
(ii) The national association of boards of pharmacy verified pharmacy program (NABP-VPP).
(iii) An accrediting organization according to R 338.532.
(iv) 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.

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.

Thank you for allowing ACHC to submit comments on this rule. If I can provide further information or clarification I can be reached at this email or my mobile at 919.621.1310.

Regards,

Jon Pritchett, Pharm.D., RPh., BCSCP
Program Director
T (855) 937-2242 x233
F (919) 785-3011

MSMS
MICHIGAN STATE MEDICAL SOCIETY

120 West Saginaw Street | East Lansing, Michigan 48823
517-337-1351 | msms@msms.org | www.msms.org

VIA email at BPL-BoardSupport@michigan.gov

September 21, 2021

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing– Boards and Committees Section
Attention: Policy Analyst
P.O. Box 30670
Lansing, MI 48909-8170

Re: Administrative Rules for Pharmacy – General Rules – Rule Set 2020-128 LR

Dear Policy Analyst:

I am writing on behalf of the Michigan State Medical Society's (MSMS) 15,000 members regarding proposed Rule Set 2020-128 LR (Pharmacy – General Rules) (the "Proposed Rule Set") which provides several updates to the Administrative Rules including requirements for the electronic transmission of non-controlled substances. MSMS's comments are related to Rules 84 and 84a and align with comments submitted by MSMS on Rule Set 2020-82 LR (Pharmacy – Controlled Substances) on September 9, 2021.

MSMS offers the following comments to the Proposed Rule Set:

R 338.584 Noncontrolled Prescriptions

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.

R 338.584a Electronic Transmission of Prescription; Waiver of Electronic Transmission

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,…

Additionally, 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.

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.

Thank you for your consideration. Should you have any questions regarding our recommendations, please contact Stacey P. Hettiger, MSMS Senior Director of Medical and Regulatory Policy, at shettiger@msms.org. MSMS appreciates the opportunity to provide comment.

Sincerely,

Julie L. Novak
Chief Executive Officer

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a~~(6)~~**(9)** of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145, 16148, 16174, 16175, 16178, 16182, 16186, 17722, 17731, 17737, 17746, 17748, 17748a, 17748b, 17751, 17753, 17757, 17760, and 17767 of the public health code, 1978 PA 368, MCL 333.16145, 333.16148, 333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.17722, 333.17731, 333.17737, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17751, 333.17753, 333.17757, 333.17760, and 333.17767, and Executive Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.501, R 338.505, R 338.513, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.539, R 338.551, R 338.555, R 338.557, R 338.559, R 338.561, R 338.563, R 338.569, R 338.575, R 338.577, R 338.582, R 338.583, R 338.584, R 338.585, R 338.586, R 338.587, and R 338.588 of the Michigan Administrative Code are amended, and R 338.531a and R 338.584a are added, as follows:

~~ADMINISTRATIVE HEARINGS~~ PHARMACY SERVICES IN MEDICAL INSTITUTIONS

PART 1. GENERAL PROVISIONS

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.

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.

PART 2. PHARMACIST LICENSES

R 338.513 Educational limited license; application and renewal; practices.

Rule 13. (1) An applicant for an educational limited license shall submit to the department a completed application on a form provided by the department with the requisite fee. In addition to satisfying the requirements of sections 16174 and 17737 of the code, MCL 333.16174 and MCL 333.17737, the applicant shall establish either of the following:

(a) That ~~he or she~~**the applicant** is actively enrolled in, or is within 180 days of ~~having graduated from~~**completing**, an approved educational program.

(b) That ~~he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by~~ **the applicant has received a Foreign Pharmacy Graduate Examination Committee (FPGEC) certification from** the ~~national association of boards of pharmacy~~ **National Association of Boards of Pharmacy** (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, ~~IL~~ **Illinois,** 60056, https://nabp.pharmacy/programs/fpgec/.)

(2) The educational limited license must be renewed annually as follows:

(a) At the time of renewal, the applicant shall submit verification to the department that he or she is actively enrolled in, or is within 180 days of ~~having graduated from~~**completing**, an approved educational program. The educational limited license is valid for 1 year.

(b) If an applicant is a graduate of a non-accredited college or school of pharmacy at the time of renewal, the applicant shall submit verification to the department from his or her preceptor that the applicant is currently in an internship program under the preceptor's supervision. The educational limited license is valid for 1 year and may be renewed 1 time.

(3) An educational limited licensee may engage in the practice of pharmacy only under the personal charge of a pharmacist.

(4) An educational limited licensee shall verify that his or her pharmacy preceptor holds a valid preceptor license prior to engaging in the practice of pharmacy if the internship hours will be submitted to the department for credit.

(5) An educational limited licensee shall notify the board within 30 days if he or she is no longer actively enrolled in an approved educational program.

(6) An applicant for an educational limited license shall meet the requirements of R 338.511.

R 338.517 Preceptor license and responsibilities.

Rule 17. (1) An applicant for licensure as a pharmacist preceptor shall submit to the department a completed application on a form provided by the department.

(2) The applicant shall satisfy both of the following:

(a) Have an unrestricted pharmacist license from this state that is in good standing for the past year.

(b) Have been engaged in the practice of pharmacy in this state for at least 1 year.

(3) A preceptor shall do all of the following:

(a) Ensure that the pharmacist on duty is supervising not more than 2 pharmacist interns at the same time. The approved preceptor is responsible for the overall internship program at the pharmacy.

(b) Determine the degree of the intern's professional skill on the topics listed in R 338.501(1)~~(i)~~**(j)** and develop a training program whereby the intern can improve his or her skill in these areas.

(c) Ensure sufficient time to instruct the intern on the topics in R 338.501(1)~~(i)~~ **(j)** and review and discuss the intern's progress on the topics in R 338.501(1)~~(i)~~**(j)**.

(d) Annually submit **to the department** training affidavits **that include the number of internship hours completed by the intern in the practice of pharmacy.** ~~and, upon completion of the training, provide comments regarding the ability of the intern to practice pharmacy without supervision on a form provided by the department.~~

R 338.519 Examinations adoption; passing scores; reexamination.

Rule 19. (1) The board adopts the North American pharmacist licensure examination (NAPLEX) developed and administered by the NABP.

(2) The board adopts the Michigan multistate pharmacy jurisprudence examination (MPJE) that is developed and administered by NABP.

(3) The passing score for the NAPLEX or the MPJE accepted for licensure will be the passing score established by the NABP.

(4) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is longer. An applicant who has not achieved a passing score on the NAPLEX may not take the NAPLEX more than 3 times in a 12-month period.

(5) An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is longer.

~~(4)~~ **(6)** If an applicant for licensure fails to pass either of these examinations, within 3 attempts, ~~he or she~~ **the applicant** shall **request preapproval from the department, after consultation with a board member, if necessary, of a live or interactive examination preparation course, or instruction with an instructor with expertise on the subject matter, for the examination that he or she failed. After participating in the course or instruction the applicant shall** provide the ~~board~~**department**~~, after the third attempt and prior to retesting,~~ **with** ~~certification~~ **proof** ~~from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.~~ **that he or she completed the course or instruction.**

~~(5) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is later. An applicant who has not achieved a passing score on the NAPLEX shall not take the NAPLEX more than 3 times in a 12-month period.~~

~~(6) An applicant who fails to pass the MPJE shall wait at least 30 days to retest or comply with the current waiting period established by NABP, whichever is later.~~

(7) An applicant ~~shall~~ **may** not sit for the NAPLEX specified in subrule ~~(5)~~**(4)** of this rule more than 5 times, unless he or she successfully repeats an approved education program, as specified in R 338.521(2)(a)(i), and provides proof of completion to the ~~board~~**department**.

(8) An applicant ~~shall~~ **may** not sit for the MPJE specified in subrule ~~(6)~~**(5)** of this rule more than 5 times, unless he or she successfully repeats an approved pharmacy law course in an educational program, as specified in R 338.521(2)(a)(i), and provides proof of completion to the ~~board~~**department**.

R 338.521 Pharmacist licensure by examination.

Rule 21. (1) An applicant for licensure as a pharmacist by examination shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) In addition to meeting the requirements of section 16174 of the code, MCL 333.16174, an applicant for licensure shall satisfy all of the following requirements:

(a) ~~Earned~~ **Have earned** either of the following:

(i) A professional degree from a school of pharmacy accredited by the ~~American council of pharmaceutical education~~ **ACPE**.

(ii) A ~~foreign pharmacy graduate examination committee certificate~~ **FPGEC certification** ~~administered by~~ **from** the NABP. **An applicant who has an FPGEC certification from NABP has met the English proficiency requirement as the**

applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.

(b) ~~Successfully passed~~ **Passed** the MPJE and the NAPLEX.

(c) Completed an internship as set forth in R 338.515.

(d) Completed a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(e) Completed a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

(f) Submitted proof to the department of meeting the English language requirement under R 338.7002b and the implicit bias training required in R 338.7004. An applicant who has an FPGEC certification from NABP has met the English proficiency requirement as the applicant's credentials and English proficiency have been evaluated and determined to be equivalent to the credentials required in this state.

(3) ~~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 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:**

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

(b) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, which includes 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.

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.

R 338.525 Relicensure of a pharmacist license; requirements.

Rule 25. (1) An applicant for relicensure whose pharmacist license has lapsed **in this state**, under ~~the provisions of sections~~ **sections** 16201(3) or (4)~~,~~ and 17733 of the code, MCL 333.16201~~(3) and (4),~~ and MCL 333.17733, as applicable, may be relicensed by complying with the following requirements as noted by (x):

For a pharmacist who has let his or her license lapse **in this state** and who is not currently licensed in another state **or a province of Canada**:	License lapsed 0-3 years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to	X	X	X

the department a completed application on a form provided by the department, with the requisite fee.			
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174~~(3)~~.		X	X
(d) Continuing education: submit proof of ~~having completed~~ **completing** 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.	X	X	X
(e) Pass MPJE: retake and pass the MPJE as provided in R 338.519.		X	X
(f) Submit proof of ~~having completed both~~ **completing** a 1-time training in identifying victims of human trafficking as required in R 338.511**,** ~~and~~ a 1-time training in opioids and other controlled substances awareness as required in R 338.3135**, and implicit bias training as required in R 338.7004**.	X	X	X
(g) Practical experience: complete 200 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of ~~applying for relicensure~~ **of being granted a limited license**.		X	
(h) Practical experience: complete 400 hours of practical experience under the personal charge of a currently			X

licensed Michigan pharmacist in or outside of Michigan, within 6 months of ~~applying for relicensure~~ **of being granted a limited license**.			
(i) Examination: pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X
~~(h)~~ **(j)** ~~Proof of license verification from another state: An applicant's license must be verified by the licensing agency of all other states of the United States in which the applicant ever held a license as a registered professional nurse. Verification must include the record 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 includes 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.**	X	X	X

(2) For purposes of subrule (1)(g) and (h) of this rule, an applicant may be granted a nonrenewable limited license to complete the practical experience.

(3) To demonstrate compliance with subrule (1)(g) or (h), the supervising pharmacist shall provide verification to the department of the applicant's completion of the experience on a form provided by the department.

(4) For a pharmacist who has let his or her pharmacist license lapse **in this state**, but who holds a current and valid pharmacist license in **good standing in** another state **or a Canadian province**:	License lapsed 0-3 Years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the	X	X	X

department a completed application on a form provided by the department, with the requisite fee.			
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174~~(3)~~.		X	X
(d) Continuing education: submit proof of ~~having completed~~ **completing** 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.	X	X	X
(e) Submit proof of ~~having completed both~~ **completing** a 1-time training in identifying victims of human trafficking as required in R 338.511**,** ~~and~~ a 1-time training in opioids and other controlled substances awareness as required in R 338.3135**, and implicit bias training as required in R 338.7004**.	X	X	X
(f) Examination: retake and pass the MPJE as provided in R 338.519.		X	X
(g) ~~Verification: submit verification from the licensing agency of all other states of the United States in which the applicant holds or has ever held a license to practice pharmacy. Verification must include the record 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**	X	X	X

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 includes 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.**			

(5) If relicensure is granted and it is determined that a sanction has been imposed by another state, the United States military, the federal government, or another country, the disciplinary subcommittee may impose appropriate sanctions under section 16174(5) of the code, MCL 333.16174.

PART 3. PHARMACY LICENSES

R 338.531 Pharmacy license; **remote pharmacy license;** applications; requirements.

Rule 31. (1) An applicant for a pharmacy license **or a remote pharmacy license** shall submit to the department a completed application on a form provided by the department together with the requisite fee.

(2) An applicant shall submit all of the following information:

(a) Certified copies of articles of incorporation or partnership certificates and certified copies of assumed name certificates, if applicable.

(b) Submission of fingerprints for the purpose of a criminal history background check required under section 17748(6) of the code, MCL 333.17748~~(6)~~.

(c)~~ Proof of registration or licensure from every state or province where the pharmacy is currently licensed or has ever held a license or registration.~~ **A federal employer identification number (FEIN) certificate.**

(d) The name and license number of the pharmacist in this state designated as the pharmacist in charge (PIC) pursuant to section 17748(2) of the code, MCL 333.17748~~(2)~~, who must have a valid and unrestricted license.

(e) The identity and address of each partner, officer, or owner, as applicable.

(f) A completed self-inspection form.

(g) If the applicant intends to provide compounding services, proof of application with an entity that satisfies the requirements of R 338.532.

(h) An inspection report that satisfies the requirements of R 338.534.

(i) If the applicant is an in-state pharmacy that intends to compound pharmaceutical products, the applicant shall submit to an inspection from an approved accrediting organization under R 338.532.

(j) If the applicant is a governmental entity, an individual must be designated as the licensee. The licensee and the pharmacist on duty shall be responsible for complying with all federal and state laws regulating the practice of pharmacy and the dispensing of prescription drugs.

(k) If the applicant is applying for a remote pharmacy license, the applicant shall submit the following:

(i) Ownership documents to demonstrate to the satisfaction of the department that the parent pharmacy and the proposed remote pharmacy share common ownership.

(ii) Copies of the policies and procedure manual required in section 17742b of the code, MCL 333.17742b.

(iii) A map showing all of the 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.

(l) If the applicant is or has ever been licensed, registered, or certified as a pharmacy by any other state, the United States military, the federal government, or another country, the applicant shall do both of the following:

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

(ii) Submit 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.

(3) The department shall issue only 1 pharmacy license per address. If an applicant has more than 1 location at which drugs are prepared or dispensed, each address location ~~shall~~ **must** obtain a separate license.

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.

R 338.533 Compounding standards and requirements; outsourcing facilities; requirements.

Rule 33. (1) The board approves and adopts by reference the compounding standards of the United States Pharmacopeia (USP), published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, ~~MD~~ **Maryland,** 20852-1790. This includes, but is not limited to, USP Chapters 795 and 797.

(2) The standards adopted by reference in subrule (1) of this rule are available at **no** cost at http://www.usp.org/compounding~~, or at cost~~ **, or at a cost of 10 cents per page** from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, ~~MI~~**Michigan,** 48909.

(3) A pharmacy that provides compounding services shall comply with all current standards adopted in subrule (1) of this rule.

(4) An outsourcing facility located in this state or that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state must be inspected and registered as an outsourcing facility by the United States Food and Drug Administration (FDA) prior to applying for a pharmacy license in this state.

(5) A licensed outsourcing facility shall submit to the board a copy of the biannual report it provided to the FDA that identifies the drugs compounded in the previous 6-month period, including a drug's active ingredients, strength, and dosage form.

(6) An outsourcing facility shall do all of the following:

(a) Compound drugs by or under the supervision of a licensed pharmacist.

(b) Compound drugs pursuant to current good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208 (~~1978~~**2021**).

(c) Ensure that a pharmacist ~~or pharmacists~~ who conducts or oversees compounding at an outsourcing facility is proficient in the practice of compounding and has acquired the education, training, and experience to maintain that proficiency by doing any of the following:

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

(iv) Being certified by a compounding certification program approved by the board.

(d) Label compounded drugs with all of the following and label compounded drugs that are patient specific with all of the following and consistent with the requirements in R 338.582:

(i) Required drug and ingredient information.

(ii) Facility identification.

(iii) The following or similar statement: "This is a compounded drug. For office use only" or "Not for resale."

(e) Ensure that bulk drug substances used for compounding meet specified FDA criteria.

(7) An outsourcing facility may compound drugs that appear on an FDA shortage list, if the bulk drug substances used to compound the drugs comply with the criteria specified in this rule.

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.~~

R 338.535 Discontinuing**, starting, or resuming** sterile compounding services; requirements to resume sterile compounding services.

Rule 35. (1) A sterile compounding pharmacy or outsourcing facility that ceases to provide sterile compounding services in this state shall notify the department within 30 days of ceasing to provide sterile compounding services.

(2) **A pharmacy shall apply for approval to start or resume sterile compounding services by submitting to the department an application on a form provided by the department together with the requisite fee.**

(3) A pharmacy shall not **start** or resume ~~providing~~ sterile compounding services in this state until the pharmacy **submits to the department an inspection report as required**

in R 338.534(3), is approved by the department**,** and is accredited or an organization satisfying the requirements of R 338.532(1) verifies that the pharmacy is USP compliant.

~~(3) A pharmacy shall apply for approval to resume sterile compounding services by submitting to the department an application on a form provided by the department together with the requisite fee.~~

(4) An outsourcing facility shall not **start or** resume providing sterile compounding services in this state until the outsourcing facility is approved by the department and verifies that it is compliant with the requirements of R 338.533(4) to (7).

R 338.536 Housing of a pharmacy.

Rule 36. (1) All professional and technical equipment and supplies and prescription drugs must be housed in a suitable, well-lighted, and well-ventilated room or department with clean and sanitary surroundings.

(2) All pharmacies shall have a prescription department that is devoted primarily to the practice of pharmacy that occupies not less than 150 square feet of space, and that includes a prescription counter that provides not less than 10 square feet of free working surface. For each additional pharmacist who is on duty at any 1 time, the free working space must be increased by not less than 4 square feet. The prescription counter must be kept orderly and clean. The space behind the prescription counter must be sufficient to allow free movement within the area and must be free of obstacles.

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee must be permanently enclosed by partitions from the floor to the ceiling. All partitions must be of substantial construction and must be securely lockable so that drugs and devices that can be sold only by a pharmacist will be unobtainable during the absence of the pharmacist. Only the area of the premises owned, leased, used, or controlled by the licensee may be identified by the terms “drugstore,” “apothecary,” or “pharmacy,” or by use of a similar term or combination of terms as listed in section 17711(2) of the code, MCL 333.17711~~(2)~~. A pharmacy department must be locked when the pharmacist is not on the premises.

R 338.537 Professional and technical equipment and supplies.

Rule 37. A pharmacy must be equipped with **both** ~~all~~ of the following:

(a) ~~Drawers, shelves, and storage cabinets.~~ **The necessary facilities, apparatus, utensils, and equipment to permit the pharmacy to provide prompt and efficient services.**

~~(b) A sink that has hot and cold running water.~~

~~(c) A refrigerator of reasonable capacity located in the pharmacy department.~~

~~(d)~~ **(b)** Current **print, electronic, or internet accessible** editions ~~or revisions~~ of the Michigan pharmacy laws and rules, and ~~not less than~~ **at least** 2 current ~~or revised~~ pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition. ~~A current electronic version of pharmacy laws, rules, and pharmacy reference texts, including accessible internet versions, meets the requirements of this subrule.~~

R 338.538 Closing pharmacy.

Rule 38. (1) A pharmacy that is ceasing operations shall return to the department the pharmacy license and the controlled substance license, if applicable, and ~~shall~~ provide the department with written notification of all of the following at least 15 days prior to closing:

(a) The effective date of closing.

(b) ~~The disposition of~~ **How** controlled substances **will be disposed**.

(c) ~~The disposition of~~ **How** non-controlled substances **will be disposed**.

(d) ~~The disposition of~~ **The location where** records and prescription files **will be stored**.

(2) A pharmacy shall comply with all applicable federal requirements for discontinuing operation as a pharmacy that dispenses controlled substances.

(3) Records must be maintained for the same amount of time that is required if the pharmacy remained open.

R 338.539 Relicensure **and renewal**.

Rule 39. (1) An applicant **with an expired license may apply** for relicensure of a pharmacy license ~~shall~~ **by** ~~submit~~ **submitting** to the department a completed application on a form provided by the department**, satisfying all the requirements for licensure in part 3 of these rules, R 338.531 to R 338.539, and paying** ~~with~~ the requisite fee.

(2) A pharmacy that **renews its license during the license renewal period** ~~has an expired license~~ shall ~~satisfy the requirements of R 338.531 to be relicensed~~ **submit to the department a completed application, on a form provided by the department, together with the requisite fee.**

PART 4. MANUFACTURER LICENSE

R 338.551 Manufacturer license; application.

Rule 51. (1) An applicant for a manufacturer license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) An applicant shall provide all of the following information:

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

(b) ~~Verification or certification from every state or province where the applicant is currently licensed or has ever held a license.~~ **A FEIN certificate.**

(c) Certified copies of articles of incorporation or certificates of partnership and assumed name certificates, if applicable.

(d) The identity and address of each partner, officer, or owner, as applicable.

(e) A completed compliance checklist for manufacturers.

(f) A list or a catalog of all drug products or devices to be manufactured by the facility.

(g) Unless exempt under section 17748(2) of the code, MCL 333.17748~~(2)~~, the name and license number of the pharmacist designated as the ~~pharmacist in charge (~~PIC~~).~~ **or the name of the facility manager. For an individual who is designated as a facility manager, the applicant shall provide proof, in the form of an affidavit, that the facility manager has achieved the following:**

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

(A) A high school diploma.

(B) A general education development certificate (GED).

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

(iii) Experience equal to either of the following:

(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.

(B) Previous or current employment as a designated representative of a manufacturer.

(iv) Employment with the applicant.

(h) A copy of the FDA certification for the site to be licensed, if an applicant is a manufacturer of biologicals.

(i) An inspection from the manufacturer's resident state board of pharmacy or verified-accredited wholesale distributors (VAWD) accreditation dated not more than 2 years prior to the application.

(j) An applicant that is or has ever been licensed, registered, or certified as a manufacturer 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) Submit 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.

(3) A separate license is required for each location where prescription drugs or devices are manufactured.

(4) ~~A pharmacy is a manufacturer and shall obtain a manufacturer license if it prepares or compounds prescription drugs for resale, compounding, or dispensing by another person in an amount that exceeds 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during a consecutive 12-month period.~~

A manufacturer who 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.

R 338.555 Federal regulation on good manufacturing practice for finished pharmaceuticals; adoption by reference; compliance.

Rule 55. (1) The board approves and adopts by reference the current good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 (~~1978~~**2021**).

(2) A manufacturer shall comply with the standards adopted in subrule (1) of this rule.

(3) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211~~, or at 10 cents per page~~ **, or at 10 cents per page** from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, ~~MI~~**, Michigan,** 48909.

R 338.557 Closure of a manufacturer.

Rule 57. (1) A manufacturer that is ceasing operations shall return the manufacturer license and the controlled substance license, if applicable, to the department, and provide the department with written notification of all of the following at least 15 days prior to closing:

(a) The effective date of closing.

(b) ~~The disposition of~~ **How** controlled substances **will be disposed**.

(c) ~~The disposition of~~ **How** non-controlled substances **will be disposed**.

(d) ~~The disposition of~~ **The location where** records and prescription files **will be stored**.

(2) A manufacturer shall comply with all applicable federal requirements for discontinuing a controlled substance business.

(3) Records must be maintained for the same amount of time that is required if the manufacturer remains open.

R 338.559 Relicensure **and renewal**.

Rule 59. (1) An applicant **with an expired license may apply** for relicensure of a manufacturer license ~~shall~~ **by** ~~submit~~ **submitting** to the department a completed application on a form provided by the department**, satisfying all the requirements for licensure in part 3 of these rules, R 338.531 to R 338.539, and paying** ~~with~~ the requisite fee.

(2) A manufacturer that **renews its license during the license renewal period** ~~has an expired license~~ shall ~~satisfy the requirements of R 338.551 in order to be relicensed~~ **submit to the department a completed application on a form provided by the department together with the requisite fee.**

PART 5. WHOLESALE DISTRIBUTOR **AND WHOLESALE DISTRIBUTOR-BROKER** LICENSE

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.~~

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.

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.

R 338.575 Closing a wholesale distributor **or wholesale distributor-broker**.

Rule 75. (1) A wholesale distributor that is ceasing operations shall return the wholesale distributor license and controlled substance license, if applicable, to the department, and shall provide the department with written notification of all of the following at least 15 days prior to closing:

(a) The effective date of closing.

(b) ~~The disposition of~~ **How** controlled substances **will be disposed**.

(c) ~~The disposition of~~ **How** noncontrolled substances **will be disposed**.

(d) ~~The disposition of~~ **The location where** records and prescription files **will be stored**.

(2) A wholesale distributor shall comply with all applicable federal requirements for discontinuing a business that handles a controlled substance.

(3) A wholesale distributor-broker that is ceasing operations shall return the wholesale distributor-broker license and provide the department with written notification of the location where records will be stored at least 15 days prior to closing.

(4) Records must be maintained for the same amount of time that is required if the wholesale distributor or wholesale distributor-broker remained open.

R 338.577 Relicensure **and renewal of wholesale distributor and wholesale distributor-broker**.

Rule 77. (1) An applicant **with an expired license may apply** for relicensure of a ~~wholesale distributor~~ license ~~shall~~ **by** ~~submit~~ **submitting** to the department a completed application on a form provided by the ~~department~~**department, satisfying all the requirements for licensure in part 3 of these rules, and paying** ~~with~~ the requisite fee.

(2) An applicant ~~for relicensure of a wholesale distributor license~~ that **renews its license during the license renewal period** ~~has expired must~~ **shall** ~~satisfy the requirements of R 338.563 in order to be relicensed.~~ **submit to the department a completed application on a form provided by the department, together with the requisite fee.**

(3) A wholesale distributor-broker seeking renewal shall submit an affidavit, at the time of the application for renewal 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 renewal.

PART 6. PRACTICE OF PHARMACY

R 338.582 Prescription drug labeling and dispensing.

Rule 82. (1) All labeling of prescription drugs must comply with the requirements of the code and sections 351 to 399f of the Federal Food, Drug, and Cosmetic Act, 21 USC 351 to 399f.

(2) All containers in which prescription medication is dispensed must bear a label that contains, at a minimum, all of the following information:

(a) Pharmacy name and address.

(b) Prescription number.

(c) Patient's name.

(d) Date the prescription was ~~most recently~~ dispensed.

(e) Prescriber's name.

(f) Directions for use.

(g) The name of the medication and the strength, unless the prescriber indicates "do not label."

(h) The quantity dispensed, if applicable.

(i) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates “do not label.”

(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed. This subrule does not apply if the prescriber indicates "do not label."

(4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed must be noted on the prescription.

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

R 338.583 Prescription drug receipts.

Rule 83. (1) The purchaser of a prescription drug shall receive, at the time the drug is delivered to the purchaser, a receipt that contains all of the following information:

(a) The brand name of the drug dispensed, if applicable, unless the prescriber indicates "do not label."

(b) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."

(c) The strength of the drug, if significant, unless the prescribed indicates "do not label."

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription.

(g) The date the prescription was ~~most recently~~ dispensed.

(h) The name of the prescriber.

(i) The name of the patient for whom the drug was prescribed.

(j) The price for which the drug was sold to the purchaser.

(2) Notwithstanding R 338.582, the information required in this rule must appear on either the prescription label or on a combination label and receipt.

(3) For prescription services that are covered by a third-party pay contract, the price included in the receipt is the amount paid by the patient.

(4) A pharmacist shall retain a copy of the receipt for a period of 90 days. The inclusion of the information required in this rule in the automated data processing system or on the written prescription form and the retention of the form constitutes retaining a copy of the receipt. The physical presence of the prescription form in the pharmacy or the ability to retrieve the information from the automated data processing system constitutes compliance with the requirement of having the name and address of the pharmacy on the form.

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

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.

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.

R 338.585 Customized patient medication package.

Rule 85. (1) A pharmacist may, with the consent of the patient, or the patient's caregiver, or a prescriber, provide a customized patient medication package (CPMP). A CPMP is a package that is prepared by a pharmacist for a specific patient and that contains 2 or more prescribed solid oral dosage forms. The CPMP is designed and labeled to indicate the day and time or period of time that the contents within each CPMP are to be taken. The person who dispenses the medication shall instruct the patient or caregiver on the use of the CPMP.

(2) If medication is dispensed in a CPMP, all of the following conditions must be met:

(a) Each CPMP must bear a readable label that states all of the following information:

(i) A serial number for the CPMP and a separate identifying serial number for each of the prescription orders for each of the drug products contained in the CPMP.

(ii) The name, strength, physical description, and total quantity of each drug product contained in the CPMP.

(iii) The name of the prescriber for each drug product.

(iv) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product in the CPMP.

(v) The date of the preparation of the CPMP.

(vi) An expiration date for the CPMP. The date must not be later than the earliest manufacturer's expiration date for any medication included in the CPMP or 60 days after the date of dispensing.

(vii) The name, address, and telephone number of the dispenser.

(viii) Any other information, statements, or warnings required for any of the drug products contained in the CPMP.

(b) A CPMP must be accompanied by any mandated patient information required under federal law. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

(c) At a minimum, each CPMP must ~~be in compliance~~ **comply** with the United States Pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, MCL 333.17706~~(2)~~, for moisture permeation requirements for a class b single-unit or unit-dose container. Each container must be either non-reclosable or so designed as to show evidence of ~~having been~~ **being** opened. Each CPMP must comply with all of the provisions of the poison prevention packaging act of 1970, 15 USC 1471 to 1477.

(d) When preparing a CPMP, the dispenser shall ~~take into account~~ **consider** any applicable compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may attend the simultaneous administration of the medications. Medications must not be dispensed in CPMP packaging in any of the following situations:

(i) The USP monograph or official labeling requires dispensing in the original container.

(ii) The drugs or dosage forms are incompatible with packaging components or each other.

(iii) The drugs are therapeutically incompatible when administered simultaneously.

(iv) The drug products require special packaging.

(e) If 2 medications have physical characteristics that make them indistinguishable from each other, then the medication must not be packaged together in the same CPMP.

(f) Medications that have been dispensed in CPMP packaging ~~shall~~**may** not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CPMP is changed, then a new appropriately labeled CPMP must be prepared for the patient.

(g) In addition to all individual prescription filing requirements, a record of each CPMP dispensed must be made and filed. At a minimum, each record must contain all of the following information:

(i) The name and address of the patient.

(ii) The serial number of the prescription order for each drug product contained in the CPMP.

(iii) Information identifying or describing the design, characteristics, or specifications of the CPMP sufficient to allow subsequent preparation of an identical CPMP for the patient.

(iv) The date of preparation of the CPMP and the expiration date assigned.

(v) Any special labeling instructions.

(vi) The name or initials of the pharmacist who prepared the CPMP.

R 338.586 Prescription records; nonapplicability to inpatient medical institution service.

Rule 86. (1) ~~A~~ **Each** prescription must be **chronologically** numbered, **and the pharmacist performing final verification before dispensing must record, manually or electronically, the prescription number, dispensing** ~~dated~~**date**, and **his or her** ~~initialed~~ **initials** ~~or electronically initialed by the pharmacist who performs the final verification prior to dispensing~~ at the time of the first filling at the pharmacy.

(2) If final product verification is completed by a pharmacy technician, both the initials of the pharmacy technician and delegating pharmacist must be recorded.

~~(2)~~ **(3)** If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, the name of the manufacturer or supplier of the drug dispensed must be indicated on the prescription.

~~(3)~~**(4)** This rule does not apply to pharmacy services provided in a medical institution.

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.

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.

From: Mollien, Charlie
To: Ditschman, Andria (LARA)
Subject: RE: Draft General Rules Public Comment 9.21.21 Public Hearing
Date: Tuesday, September 21, 2021 4:00:40 PM

Andria,

One additional comment. 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.

Charlie Mollien

From: Mollien, Charlie
Sent: Tuesday, September 21, 2021 3:48 PM
To: Ditschman, Andria (LARA) <DitschmanA@michigan.gov>
Subject: Draft General Rules Public Comment 9.21.21 Public Hearing

Andria,

Please see attached comments for 2020-128-LR related to the Pharmacy General Rules.

Thank you,

Charlie Mollien

CVSHealth

Deeb D. Eid, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 616-490-7398

September 20th, 2021

Andria Ditschman, JD
Senior Policy Analyst
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Re: CVS Health Comments Rules Public Hearing for Pharmacy General Rules (MOAHR #2020-128 LR)

Dear Andria and Board Members:

I am writing to you in my capacity as Advisor of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in Michigan through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the proposed rules for Pharmacy General Rules regulations. We would also like to thank the Department and Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns, and pharmacy technicians serving Michigan's patients.

CVS Health *supports* the majority of updates the Department and Board have proposed to streamline and modernize the General rules. These changes include licensing for pharmacists, pharmacies, and the practice of pharmacy.

There are a few sections we suggest could be strengthened to better align with national trends, improve patient safety, and overall outcomes. These recommended changes can be found in the **Appendix section** which highlights the rules, comments, proposed language, and any citations or additional information or questions to consider.

CVS Health appreciates the opportunity to submit comments for the Board's review. Please contact me directly at 616-490-7398 if you have any questions.

Sincerely,

Deeb D. Eid, PharmD, RPh
Advisor, Pharmacy Regulatory Affairs
CVS Health
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Appendix

1. Suggested Rule Language Changes:

Part 3 Pharmacy Licenses

R338.531a Remote Pharmacy waiver from milage requirement

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 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.

(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.

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.

Adding in the language in green 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.

CVSHealth

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Citations:

1. American Society of Health-System Pharmacists. The consensus of the Pharmacy Practice Model Summit. Am J Health-Syst Pharm. 2011; 68:1148-52. http://www.ajhp.org/content/68/12/1148.full.pdf (Accessed 2021 Sept 21).
2. National Association of Boards of Pharmacy. The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act). 2021. Available from: https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/. (Accessed 2021 Sept 21).
3. APhA Policy Manual. House of Delegates Policy and Procedure Manual. https://aphanet.pharmacist.com/policy-manual?key=telepharmacy&op=Search. (Accessed 2021 Sept 21).
4. Arizona State Board of Pharmacy ST 32-1961.01 Pharmacies; Remote Dispensing. Available from: https://pharmacy.az.gov/ (Accessed 2021 Sept 21).
5. Illinois State Board of Pharmacy ADC 68-1330.510 Telepharmacy. Available from: https://www.idfpr.com/profs/pharm.asp (Accessed 2021 Sept 20).
6. Idaho State Board of Pharmacy 24.36.01.302 Drug Outlets That Dispense Drugs to Patients without an Onsite Pharmacist or Prescriber. Available from: https://bop.idaho.gov/(Accessed 2021 Sept 15).
7. Qato DM et. al. 'Pharmacy deserts' are prevalent in Chicago's predominantly minority communities, raising medication access concerns. Health Aff (Millwood). 2014 Nov;33(11):1958-65. doi: 10.1377/hlthaff.2013.1397. PMID: 25367990.

2. <u>Suggested Rule Language Changes:</u>

Part 6 Practice of Pharmacy
Rule 88.
R338.588 Automated devices

(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]

Adding in clarifying language to allow for use of automated devices as patient pick-up options within the premises of a licensed pharmacy is recommended.

Citations/Evidence:

1. Yeo YL, Chang CT, Chew CC, Rama S. Contactless medicine lockers in outpatient pharmacy: A safe dispensing system during the COVID-19 pandemic. Res Social Adm Pharm. 2021;17(5):1021-1023. doi:10.1016/j.sapharm.2020.11.011

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2. Arizona ADC R4-23-614 Automated Storage and Distribution System. https://qa.azsos.gov/public_services/Title_04/4-23.htm
3. California ADC 16-1713 Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy. https://www.pharmacy.ca.gov/laws_regs/1711_1713_1715_1_oa.pdf
4. Montana ADC 24.174.839 Alternate delivery of prescriptions. https://rules.mt.gov/gateway/ruleno.asp?RN=24%2E174%2E839

From: BPL-BoardSupport
To: Ditschman, Andria (LARA)
Subject: FW: Public Comment on Pharmacy General Rules 2020-128 LR
Date: Thursday, September 2, 2021 11:40:31 AM
Attachments: Comments on General Rules.docx

From: Rose M Baran <RoseBaran@ferris.edu>
Sent: Thursday, September 2, 2021 11:39 AM
To: BPL-BoardSupport <BPL-BoardSupport@michigan.gov>
Subject: Public Comment on Pharmacy General Rules 2020-128 LR

Attention: Policy Analyst
Please find attached public comment on Pharmacy General Rules 2020-128 LR.
Thanks,
Rose Baran

Comments on Board of Pharmacy General Rules 2020-128 LR
Rose Baran Pharm. D.

Comments on General Rules

Rule 338.584
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.