

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

Filed with the secretary of state on February 22, 2022

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(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 16141, 16145, 16148, 16174, 16175, 16178, 16182, 16186, 16204, 16205, 16215, 16287, 17707, 17721, 17722, 17731, 17737, 17739, 17742a, 17742b, 17746, 17748, 17748a, 17748b, 17748e, 17751, 17753, 17754a, 17757, 17760, 17767, and 17775 of the public health code, 1978 PA 368, MCL 333.16141, 333.16145, 333.16148, 333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.16204, 333.16205, 333.16215, 333.16287, 333.17707, 333.17721, 333.17722, 333.17731, 333.17737, 333.17739, 333.17742a, 333.17742b, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17748e, 333.17751, 333.17753, 333.17754a, 333.17757, 333.17760, 333.17767, and 333.17775 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, R 338.583a, and R 338.584a are added, as follows:

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 an individual with the intent to sign the record. An electronic signature is a unique identifier protected by appropriate security measures that 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.

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

(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.

(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.
- (1) "Written" includes both paper and electronic forms.
- (2) Unless otherwise defined in these rules, 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 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 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) Inspections in subrule (1) of this rule 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.

## 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 the applicant is actively enrolled in, or is within 180 days of completing, an approved educational program.
- (b) That the applicant has received a Foreign Pharmacy Graduate Examination Committee (FPGEC) certification from the National Association of Boards of Pharmacy

(NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, Illinois, 60056, [https://nabp.pharmacy/programs/fpgec/.](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 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)(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)(j) and review and discuss the intern's progress on the topics in R 338.501(1)(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.

#### 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.

(6) If an applicant for licensure fails to pass either of these examinations, within 3 attempts, 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 department with proof that he or she completed the course or instruction.

(7) An applicant may not sit for the NAPLEX specified in subrule (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 department.

(8) An applicant may not sit for the MPJE specified in subrule (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 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) Have earned either of the following:

(i) A professional degree from a school of pharmacy accredited by the ACPE.

(ii) A FPGEC certification 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) 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 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) He or she holds a license in good standing as a pharmacist in another state and submits the NABP licensure transfer report to the department.

(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) 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) 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 sections 16201(3) or (4) and 17733 of the code, MCL 333.16201 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 the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(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.		X	X
(d) Continuing education: submit proof of 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 completing a 1-time training in identifying victims of human trafficking as required in R 338.511, 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 being granted a limited license.		X	
(h) Practical experience: complete 400 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of being granted a limited license.			X
(i) Examination: pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X
(j) 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	License lapsed 0-3 Years	License lapsed more than 3 years,	License lapsed 8 or more years
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state, but who holds a current and valid pharmacist license in good standing in another state or a Canadian province:		but less than 8 years	
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(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.		X	X
(d) Continuing education: submit proof of 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 completing a 1-time training in identifying victims of human trafficking as required in R 338.511, 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) 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.	X	X	X

<p>(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.</p>			
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(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.

(c) 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, 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.

(1) 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 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 and explanation of the services or availability of services that will be offered at the remote pharmacy or otherwise not readily available to patients 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, 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 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, 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 (2021).

(c) Ensure that a pharmacist 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) Unless accredited by a national accrediting organization, recognized by the board, an applicant for licensure or renewal of an in-state or out-of-state pharmacy that will provide sterile compounded pharmaceuticals in this state shall have an inspection and submit 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 1 of the following:

- (a) The department.
- (b) The NABP-Verified Pharmacy Program (NABP-VPP).
- (c) An accrediting organization according to R 338.532.
- (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.

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 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.

(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. 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 of the following:

(a) The necessary facilities, apparatus, utensils, and equipment to permit the pharmacy to provide prompt and efficient services.

(b) Current print, electronic, or internet accessible editions of the Michigan pharmacy laws and rules, and at least 2 current pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition.

#### 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 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) How controlled substances will be disposed.

(c) How non-controlled substances will be disposed.

(d) 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 by 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 the requisite fee.

(2) A pharmacy that renews its license during the license renewal period 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.

(b) 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, the name and license number of the pharmacist designated as the 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 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 (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 from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan, 48909.

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) How controlled substances will be disposed.

(c) How non-controlled substances will be disposed.

(d) 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 by 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 the requisite fee.

(2) A manufacturer that renews its license during the license renewal period shall 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 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).

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 all of the following:

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

(b) 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.

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

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

- (f) Provide a completed compliance checklist.
- (g) Provide a FEIN certificate.
- (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.
- (i) Unless exempt under section 17748(2) of the code, MCL 333.17748, provide the name and the license number of the pharmacist designated as the PIC or the name of the facility manager. For individuals 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 GED.
    - (C) A parent-issued diploma for home schooled individuals.
    - (D) Completion of post-secondary education, including an associate's, bachelor's, or 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 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.

(6) The records described in subrules (1) 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, 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 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.

(7) A wholesale distributor shall retain the records described in this rule 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.

#### 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) How controlled substances will be disposed.
- (c) How noncontrolled substances will be disposed.
- (d) 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 license by 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, and paying the requisite fee.

(2) An applicant that renews its license during the license renewal period shall 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 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 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 338.583a 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.

#### 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; 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 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 (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 pharmacy shall keep the original prescription record 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 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.

(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 the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:

(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 the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement 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 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 also meets 1 of the following:

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

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

(iii) 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.

#### 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 comply with the United States Pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, MCL 333.17706, 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 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 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 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) Each prescription must be chronologically numbered, and the pharmacist performing final verification before dispensing must record, manually or electronically, the prescription number, dispensing date, and his or her initials 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.

(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.

(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 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 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 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 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. 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 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 for 5 years. Data older than 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 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.

(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 under the control 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, 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.