STATE OF MICHIGAN
JOCELYN BENSON, SECRETARY OF STATE
DEPARTMENT OF STATE
LANSING

February 29, 2024

NOTICE OF FILING

ADMINISTRATIVE RULES

To: Secretary of the Senate
Clerk of the House of Representatives
Joint Committee on Administrative Rules
Michigan Office of Administrative Hearings and Rules (Administrative Rule #22-008-LR)
Legislative Service Bureau (Secretary of State Filing #24-02-04)
Department of Licensing and Regulatory Affairs

In accordance with the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6, this is to advise you that the Michigan Office of Administrative Hearings and Rules filed Administrative Rule #2022-008-LR (Secretary of State Filing #24-02-04) on this date at 1:11 P.M. for the Department of Licensing and Regulatory Affairs entitled, "Pharmacy – General Rules".

These rules become effective immediately after 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.

Sincerely,

Jocelyn Benson
Secretary of State

Lashana Threlkeld /CK

Lashana Threlkeld, Departmental Supervisor
Office of the Great Seal

Enclosure

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
MICHIGAN OFFICE OF ADMINISTRATIVE HEARINGS AND RULES
SUZANNE SONNEBORN
EXECUTIVE DIRECTOR

MARLON I. BROWN, DPA
ACTING DIRECTOR

CK

February 29, 2024

The Honorable Jocelyn Benson
Secretary of State
Office of the Great Seal
Richard H. Austin Building – 1st Floor
430 W. Allegan
Lansing, MI 48909

Dear Secretary Benson:

Re: Administrative Rules – Michigan Office of Administrative Hearings and Rules
Administrative Rules #: 2022-8 LR

The Michigan Office of Administrative Hearings and Rules received administrative rules, dated October 25, 2023 for the Department of Licensing and Regulatory Affairs **"Pharmacy-General Rules".** We are transmitting these rules to you pursuant to the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6.

Sincerely,

Michigan Office of Administrative Hearings and Rules

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

MARLON I. BROWN, DPA
DIRECTOR

CERTIFICATE OF ADOPTION

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, 17744f, 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, 333.17744f, 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 338.486, R 338.501, R 338.505, R 338.511, R 338.513, R 338.515, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.531a, R 338.532, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.551, R 338.555, R 338.557, R 338.559, R 338.563, R 338.569, R 338.571, R 338.575, R 338.577, R 338.583, R 338.583a, R 338.584, R 338.585, R 338.586, R 338.587, R 338.588, R 338.589, and R 338.590 of the Michigan Administrative Code are amended, and R 338.534a, R 338.588a, R 338.588b, and R 338.591 are added.

Date: 08/17/2023

Adopted by: Marlon I Brown

Marlon I. Brown, DPA
Acting Director
Department of Licensing and Regulatory Affairs

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARLON I. BROWN, DPA
ACTING DIRECTOR

LEGAL CERTIFICATION OF RULES

I certify that I have examined the attached administrative rules, dated October 25, 2023, in which the Department of Licensing and Regulatory Affairs proposes to modify a portion of the Michigan Administrative Code entitled "Pharmacy—General Rules" by:

- Amending R 338.486, R 338.501, R 338.505, R 338.511, R 338.513, R 338.515, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.531a, R 338.532, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.551, R 338.555, R 338.557, R 338.559, R 338.563, R 338.569, R 338.571, R 338.575, R 338.577, R 338.583, R 338.583a, R 338.584, R 338.585, R 338.586, R 338.587, R 338.588, R 338.589, and R 338.590.
- Adding R 338.534a, R 338.588a, R 338.588b, and R 338.591.

The Legislative Service Bureau has approved the proposed rules as to form, classification, and arrangement.

I approve the rules as to legality pursuant to the Administrative Procedures Act, MCL 24.201 *et seq.* and Executive Order No. 2019-6. In certifying the rules as to legality, I have determined that they are within the scope of the authority of the agency, do not violate constitutional rights, and are in conformity with the requirements of the Administrative Procedures Act.

Dated: October 31, 2023

Michigan Office of Administrative Hearings and Rules

By: Ashlee N. Lynn

Ashlee N. Lynn,
Attorney

LEGISLATIVE SERVICE BUREAU
Since 1941

Legal Division

Kevin H. Studebaker, Director

CERTIFICATE OF APPROVAL

On behalf of the Legislative Service Bureau, and as required by section 45 of the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.245, I have examined the proposed rules of the Department of Licensing and Regulatory Affairs dated October 25, 2023, amending R 338.486, R 338.501, R 338.505, R 338.511, R 338.513, R 338.515, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.531a, R 338.532, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.551, R 338.555, R 338.557, R 338.559, R 338.563, R 338.569, R 338.571, R 338.575, R 338.577, R 338.583, R 338.583a, R 338.584, R 338.585, R 338.586, R 338.587, R 338.588, R 338.589, and R 338.590 and adding R 338.534a, R 338.588a, R 338.588b, and R 338.591 of the Department's rules entitled "Pharmacy – General Rules." I approve the rules as to form, classification, and arrangement.

Dated: October 31, 2023

LEGISLATIVE SERVICE BUREAU

By _____

Rachel M. Hughart,
Legal Counsel

Michigan Legislature
124 W. Allegan Street, 3rd Floor • P.O. Box 30036 • Lansing, MI 48909-7536 • (517) 373-9425 • Fax: (517) 373-5642

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

Filed with the secretary of state on February 29, 2024

These rules become effective immediately after 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, 17744f, 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, 333.17744f, 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 338.486, R 338.501, R 338.505, R 338.511, R 338.513, R 338.515, R 338.517, R 338.519, R 338.521, R 338.523, R 338.525, R 338.531, R 338.531a, R 338.532, R 338.533, R 338.534, R 338.535, R 338.536, R 338.537, R 338.538, R 338.551, R 338.555, R 338.557, R 338.559, R 338.563, R 338.569, R 338.571, R 338.575, R 338.577, R 338.583, R 338.583a, R 338.584, R 338.585, R 338.586, R 338.587, R 338.588, R 338.589, and R 338.590 of the Michigan Administrative Code are amended, and R 338.534a, R 338.588a, R 338.588b, and R 338.591 are added, as follows:

PHARMACY SERVICES IN MEDICAL INSTITUTIONS

R 338.486 "Medical institution" and "pharmacy services" defined; pharmacy services in medical institutions.

Rule 16. (1) As used in this rule:

(a) "Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, freestanding surgical outpatient facility, hospice, or other health facility that is licensed or approved by the state, which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services for patients in a medical institution, associated with the practice of pharmacy.

(2) Pharmacy services in a medical institution must be directed and provided by a licensed pharmacist.

(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of patients of a medical institution are supervised by a pharmacist who is on the premises of the medical institution.

(4) The pharmacist who directs the pharmacy services shall develop, implement, supervise, and coordinate the services provided, including, at a minimum, all of the following:

(a) Dispensing medications in a form that minimizes additional preparation before administration to the patient, including the admixture of parenterals.

(b) Obtaining the prescriber's original medication order, a direct carbonized copy, an electromechanical facsimile, or other electronic order transmission. Security measures must be in place to ensure that system access by unauthorized individuals is not allowed.

(c) Interpreting and reviewing the prescriber's medication orders and communicating problems with these orders to the prescriber before the administration of first doses. If the interpretation and review will cause a delay that would adversely affect a patient's medical condition, a limited number of medications may be stocked at the patient care areas for the administration of first doses. Medications must be provided in a manner that ensures security and immediate availability, including sealed or secured medication kits, carts, or treatment trays. A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

(d) Furnishing medications for administration to registered patients under R 338.588 and 338.588b.

(e) Monitoring medication therapy to promote positive patient outcomes while evaluating clinically significant chemical and therapeutic incompatibilities.

(f) Establishing the specifications for the procurement of all pharmaceuticals and related biologicals and chemicals approved for use in the medical institution.

(g) Inspecting all areas in the medical institution where medications are stored to verify compliance with the standards for the safe use and storage of the medications, not less than once every 6 months.

(h) Maintaining proper security for all medications stored or maintained within the medical institution.

(i) Providing educational programs that include, but are not limited to, medications used by the medical institution and their safe use.

(j) Providing a process by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The process must comply with all of the following:

(i) Minimize the potential for medication error.

(ii) During the absence of a pharmacist, the services of a pharmacist must be available on an on-call basis.

(iii) Only a limited number of medications that are packaged in units of use must be available.

(iv) The medications must be approved and reviewed periodically as determined necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution.

(v) The medication must be maintained in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy.

(vi) Each medication must be labeled to include the name of the medication; the strength; the expiration date, if dated; and the lot number.

(vii) A written order and a proof of removal and use document are obtained for each medication unit removed and reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent.

(viii) The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are allowed to remove the medication.

(ix) A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) On the recommendation of an interdisciplinary practitioners' committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee not less than quarterly to conduct assigned responsibilities.

(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient, or a unique identifier, must be labeled on the medication container. The container may be the individual patient's assigned medication drawer. The directions for use must be on the label of the container if the directions are not communicated in another effective manner. If the medication is to be self-administered, then directions for use must be on the container. The provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

(7) A pharmacist shall supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, MCL 333.7101 to 333.7125, dispensed to patients. However, medications in single-unit packages and intravenous solutions that are designed to be tamper-evident, and show no evidence that tampering has occurred, may be returned to stock. Medications that leave the medical institution or its legal affiliates must not be returned to stock for dispensing.

(8) The licensed pharmacist that directs pharmacy services in the medical institution shall make the policies and procedures required by this rule available to an agent of the board, on request.

PART 1. GENERAL PROVISIONS

R 338.501 Definitions.

Rule 1. (1) As used in these rules:

(a) "ACPE" means Accreditation Council for Pharmacy Education.

(b) "Approved education program" means a school of pharmacy that is accredited by or has candidate status by the ACPE.

(c) "Board" means the Michigan board of pharmacy, created in section 17721 of the code, MCL 333.17721.

(d) "Code" means the public health code, 1978 PA 368, MCL 333.1101 to 333.25211.

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

(i) On receipt of a prescription for a specific patient.

(ii) On 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.

(f) "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 under 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.

(g) "CPMP" means customized patient medication package that is prepared by a pharmacist for a specific patient and contains 2 or more prescribed solid oral dosage forms.

(h) "DEA" means the Federal Drug Enforcement Administration.

(i) "Department" means the department of licensing and regulatory affairs.

(j) "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.

(k) "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.

(l) "FDA" means the United States Food and Drug Administration.

(m) "FEIN" means a federal employer identification number.

(n) "FPGEC" means the Foreign Pharmacy Graduate Examination Committee.

(o) "GED" means a general education development certificate.

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

(q) "NABP" means the National Association of Boards of Pharmacy.

(r) "NABP-VPP" means the NABP Verified Pharmacy Program.

(s) "NAPLEX" means the North American pharmacist licensure examination.

(t) "PIC" means pharmacist in charge.

(u) "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.

(v) "USP" means the United States Pharmacopeia.

(w) "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.

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

(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning as 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 under 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 distribution 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) Purchasing data, other than shipment data, and the current and historical selling price of a drug.

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

(d) Research data, other than research data that confirms the appropriate use of controlled substances for research purposes, or research data for accountability for reconciliation of prescription drug inventories.

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

PART 2. PHARMACIST LICENSES

R 338.511 Training standards for identifying victims of human trafficking; requirements.

Rule 11. (1) Under section 16148 of the code, MCL 333.16148, the individual seeking licensure or who is licensed shall have completed training in identifying victims of human trafficking that meets the following standards:

(a) Training content must cover all of the following:

(i) Understanding the types and venues of human trafficking in the United States.

(ii) Identifying victims of human trafficking in healthcare settings.

(iii) Identifying the warning signs of human trafficking in healthcare settings for adults and minors.

(iv) Identifying resources for reporting the suspected victims of human trafficking.

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

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

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

(iii) Training obtained in an educational program that has been approved by the board for initial licensure, or by a college or university.

(iv) Reading an article related to the identification of victims of human trafficking that meets the requirements of subdivision (a) of this subrule and is published in a peer-review journal, healthcare journal, or professional or scientific journal.

(c) Acceptable modalities of training may include any of the following:

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

(2) The department may select and audit an individual and request documentation of proof of completion of training. If audited by the department, the individual shall provide an acceptable proof of completion of training, including either of the following:

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

(b) A self-certification statement by the individual. The certification statement must include the individual's name and 1 of the following:

(i) For training completed under subrule (1)(b)(i) to (iii) of this rule, the date, training provider name, and name of training.

(ii) For training completed under subrule (1)(b)(iv) of this rule, the title of article, author, publication name of the peer-review journal, healthcare journal, or professional or scientific journal, and the date, volume, and issue of publication as applicable.

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 333.17737, the applicant shall establish 1 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 FPGEC certification from the NABP Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, 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 the applicant 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 the licensee's pharmacy preceptor holds a valid preceptor license before 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 the licensee 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 and R 338.7004.

R 338.515 Internship requirements.

Rule 15. (1) An applicant for a pharmacist license shall acquire a minimum of 1,600 internship hours, which may be completed through an educational program, under the personal charge of a preceptor, through a preapproved unconventional internship, or through an educational program outside of the United States under subrule (2) of this rule. An internship is subject to all of the following:

(a) Not more than 40 hours per week may be earned.

(b) An unconventional internship requires prior board approval and is limited to a maximum of 400 hours, with a maximum of 16 hours earned per week, and not more than 40 hours earned per week when the intern's pharmacy school is not in session. As used in this subdivision, "unconventional internship" means an educational program of professional and practical experience involving the pharmacy or related pharmaceutical experiences which, through on-the-job training, provides knowledge useful to the practice of the profession of pharmacy.

(c) The licensed pharmacy preceptor, an approved education program, or other individual previously approved by the board shall verify internship hours.

(d) An individual participating in a preapproved unconventional internship shall annually submit to the department an affidavit from the internship supervisor that includes the type of activities performed and the number of internship hours completed.

(e) The internship must provide professional and practical experience.

(2) An individual who graduated from a program outside the United States may petition the board for approval of a maximum of 1,400 internship hours if an internship is not completed through an approved educational program or under the personal charge of a preceptor licensed in this state. The internship hours must be obtained through an educational program experience.

(3) An individual shall obtain an educational limited license under R 338.513 before starting an internship that includes the practice of pharmacy in this state.

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)(u) and develop a training program where the intern can improve the intern's skill in these areas.

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

(4) Unless the hours are completed in an educational program, the preceptor shall submit to the department a training affidavit that includes 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 NAPLEX developed and administered by the NABP.

(2) The passing score for the NAPLEX accepted for licensure is the passing score established by the NABP.

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

(4) If an applicant for licensure fails to pass the NAPLEX 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 the applicant failed. After participating in the course or instruction the applicant shall provide the department with proof that the applicant completed the course or instruction.

(5) An applicant may not sit for the NAPLEX specified in subrule (4) of this rule more than 5 times, unless the applicant successfully repeats an approved education 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; R 338.7001 to R 338.7005; and any other rules promulgated under the code, an applicant for licensure shall satisfy all of the following requirements:

(a) Obtain one 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 that 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.

(iii) A score transfer from NABP if the applicant has been licensed in another state for 1 day to 1 year.

(b) Pass the NAPLEX.

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

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

(f) Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.

(3) An applicant that is or has ever been licensed, registered, or certified in a health profession or specialty by another 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, including 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 that has never held a pharmacist license in this state and is licensed in another state or Canada, may apply for licensure as a pharmacist by endorsement by submitting to the department a completed application on a form provided by the department with the requisite fee. An applicant that meets the requirements of this rule, R 338.7001 to R 338.7005, and any other rules promulgated under the code 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) The applicant holds a license in good standing as a pharmacist in another state and submits the NABP licensure transfer report to the department.

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

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

(B) The applicant 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.

(C) If the applicant held a pharmacist license for less than 1 year in Canada, the applicant 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) Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.

(c) An applicant that is or has ever been licensed, registered, or certified in a health profession or specialty by another 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, including 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) The applicant 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) The applicant 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) The applicant completes a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

(2) An applicant that 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 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 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) Submit to the department a completed application on a form provided by the department with the requisite fee.	X	X	X
(b) Establish that the applicant is of good moral character as that term is	X	X	X

defined in, and determined under, 1974 PA 381, MCL 338.41 to MCL 338.47.			
(c) Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) Submit proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately before the application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years after the date of the application to complete the deficient hours. The application must be held and the license may not be issued until the continuing education requirements are met.	X	X	X
(e) Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.		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) Complete 200 hours of practical experience under the personal charge of a pharmacist currently licensed in this state who is located in or outside of this state, within 6 months after being granted a limited license.		X	
(h) Complete 400 hours of practical experience under the personal charge of a pharmacist currently licensed in this state who is located in or outside of this state, within 6 months after being granted a limited license.			X
(i) Retake and pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X

(j) An applicant that is or has ever been licensed, registered, or certified in a health profession or specialty by another 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, including 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) As used in subrule (1)(g) and (h) of this rule, an applicant may be granted a non-renewable 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) Submit to the department a completed application on a form provided by the department with the requisite fee.	X	X	X
(b) Establish that the applicant is of good moral character as that term is defined in, and determined under, 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) Submit proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately before the application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years after the date of the application to complete the deficient	X	X	X

hours. The application must be held and the license may not be issued until the continuing education requirements are met.			
(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) Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.		X	X
(g) An applicant that is or has ever been licensed, registered, or certified in a health profession or specialty by another 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, including 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

(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 FEIN certificate.

(d) The name and license number of the pharmacist in this state designated as the PIC under section 17748(2) of the code, MCL 333.17748, who must have a valid and unrestricted license. If a PIC is unable to fulfill his or her duties for 120 consecutive days, the pharmacy shall appoint a new PIC and notify the department as required in section 17748(4) of the code, MCL 333.17748.

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

(f) A completed self-inspection form.

(g) If the applicant is an out-of-state pharmacy that will not provide sterile compounding services, an inspection report that satisfies the requirements of R 338.534.

(h) If the applicant is an in-state pharmacy that intends to compound sterile pharmaceutical products, the applicant shall submit to an inspection under R 338.534a.

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

(j) 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.

(k) If the applicant is or has ever been licensed, registered, or certified as a pharmacy by another 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 after receipt of the denial, the applicant notifies the department that it is requesting a hearing on the matter.

R 338.532 Sterile compounding accrediting organizations; board approval; inspection entities.

Rule 32. (1) The board shall approve, under section 17748a of the code, MCL 333.17748a, accrediting organizations or inspection entities for pharmacies that compound pharmaceuticals according to standards adopted by reference in R 338.533.

(2) The department shall post on its website, the list of organizations approved under subrule (1) of this rule.

(3) An organization may petition the board for approval under subrule (1) of this rule. The petition must include, but is not limited to, all of the following:

(a) Requirements for accreditation or compliance.

(b) Requirements for inspectors.

(c) Training provided to inspectors.

(d) Copy of the most current inspection form.

(e) The length of accreditation.

(f) Agreement and plan to share results of inspections with the department.

(4) If the board approves the petition, the approval is valid for 3 years after the date of approval. The organization may submit a petition that complies with subrule (3) of this rule to seek continuing approval.

(5) The board may rescind approval of an organization upon just cause. The rescission will not immediately affect the compliance of a pharmacy using the accreditation. Within 12 months after the rescission date or by the next licensure renewal date, whichever is later, the accreditation is void, and a pharmacy shall obtain accreditation or an inspection from an organization that satisfies subrule (1) of this rule.

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

Rule 33. (1) The board approves and adopts by reference the compounding standards of USP, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852-1790. This includes USP Chapters 795 (revised 2023) and 797 (revised 2023), with the exception of flavoring.

(2) The standards adopted by reference in subrule (1) of this rule are available at a cost of $250.00 at http://www.usp.org/compounding, or can be viewed at the 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 the standards adopted in subrule (1) of this rule.

(4) An outsourcing facility located outside of this state that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state shall be inspected and registered as an outsourcing facility by the FDA before applying for a pharmacy license in this state.

(5) An outsourcing facility located within this state that is applying for licensure as a pharmacy shall complete both of the following:

(a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure.

(b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess adherence to the current and as amended good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208.

(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 under current good manufacturing practices for finished pharmaceuticals set forth in 21 CFR 211.1 to 211.208.

(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 and compounded drugs that are patient specific in compliance with the requirements in R 338.582 and include all of the following:

(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 Out-of-state pharmacy licensure inspection; in-state

pharmacy licensure renewal inspection.

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 resident state board of pharmacy inspection or an NABP-VPP inspection that was performed within the last 2 years before the date of application.

(2) Unless accredited by a national accrediting organization, recognized by the board, an applicant for renewal of an in-state pharmacy license, or an applicant for an initial or renewal of an out-of-state pharmacy license, 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-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 338.534a In-state initial pharmacy license inspections.

Rule 34a. (1) An in-state pharmacy that will not compound sterile pharmaceutical products that is applying for initial licensure shall be inspected by the department or its designee before licensure.

(2) An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products shall complete both of the following:

(a) Obtain an inspection from the department or its designee for the purpose of meeting R 338.536 and R 338.537 for initial licensure.

(b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess USP compliance or achieve accreditation from 1 of the entities listed in R 338.534(2)(a) to (c).

(3) Approval to engage in sterile compounding will end 6 months after initial licensure if a subsequent inspection to assess USP compliance or accreditation is not successful.

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 after 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(2), 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 the department 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 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 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) Except as allowed in R 338.588a(2), pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee shall 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 are 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. (1) A pharmacy shall be equipped with both of the following:

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

(b) Current print, electronic, or unabridged computerized versions of the pharmacy laws and rules of this state, and not less than 2 current pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition, or other information necessary for the delivery of safe and effective practice of pharmacy.

(2) In addition to subrule (1) of this rule, a pharmacy that dispenses drugs shall maintain, at a minimum, all of the following equipment:

(a) A sink with running water.

(b) A refrigerator for the exclusive use of prescription drugs. Personal or food items must not be stored in the refrigerator. Refrigeration must be capable of maintaining temperature within a range compatible with the proper storage of drugs requiring refrigeration or freezing. Temperatures must be monitored at all times for out-of-range temperatures during business closure.

(c) A telephone.

R 338.538 Closing pharmacy.

Rule 38. (1) A pharmacy that is ceasing operations shall provide the department with written notification of all of the following not less than 15 days before 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.

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 under 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. If a PIC or facility manager is unable to fulfil his or her duties for 120 consecutive days, the pharmacy shall appoint a new PIC or facility manager and notify the department as required in section 17748(4) of the code, MCL 333.17748. 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 GED.
(C) A parent-issued diploma for home schooled individuals.
(D) Completion of post-secondary education, including either an associate's, bachelor's, 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 FDA, or manufacturer's resident state board of pharmacy, that is dated not more than 2 years before application or current NABP drug distributor accreditation.

(j) An applicant that is or has ever been licensed, registered, or certified as a manufacturer by another 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)(g) of this rule to the department within 30 days after 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 and as amended good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR 211.1 to 211.208 (2022).

(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 Closing 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 not less than 15 days before 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 4 of these rules, R 338.551 to R 338.559, 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 338.563 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 under 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 another 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, including 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) 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. If a PIC or facility manager is unable to fulfil his or her duties for 120 consecutive days, the pharmacy shall appoint a new PIC or facility manager and notify the department as required in section 17748(4) of the code, MCL 333.17748. 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 NABP drug distributor accreditation or of a wholesale distributor-broker.

(iv) Current employment with the applicant.

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

(j) If a wholesale distributor-broker, submit an affidavit, at the time of the application for initial licensure, that the applicant facilitates deliveries or trades for not less than 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.

(3) A wholesale distributor or wholesale distributor-broker that changes its facility manager shall submit all of the information required in subrule (2)(h) of this rule to the department within 30 days after 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 individuals 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 where the oldest stock of a prescription drug is distributed first. The procedure may allow 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, including 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 are 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 individuals 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 not less than 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 maintained 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 maintained at a central location apart from the site must be made available for inspection within 2 working days after 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 this state shall request the transaction history, transaction statement, or transaction information for the drugs supplied.

R 338.571 Facility requirements.

Rule 71. (1) A wholesale distributor that has physical custody or control of the prescription drugs or devices shall satisfy all of the following facility requirements:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.

(b) Have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(c) Have a quarantine area for the storage of prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, adulterated, or that are in immediate or sealed secondary containers that are opened.

(d) Be maintained in a clean and orderly condition.

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(f) Be secure from unauthorized entry by complying with all of the following:

(i) Access from outside the premises must be kept to a minimum and be well-controlled. The outside perimeter of the premises must be well-lighted. Entry into areas where prescription drugs or devices are held must be limited to authorized personnel.

(ii) Be equipped with an alarm system to detect entry after hours.

(iii) Be equipped with a security system that provides protection against theft and diversion. If appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(2) All prescription drugs or devices must be stored at temperatures and under appropriate conditions under the label requirements pursuant to the requirements set forth in the current edition of the USP compendium. If storage requirements are not established for a prescription drug, the drug may be held at a controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment devices, or logs must be utilized to document the proper storage of 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 provide the department with written notification of all of the following not less than 15 days before 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 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 not less than 15 days before 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 5 of these rules, R 338.563 to R 338.577, 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 not less than 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 338.583 Prescription drug receipts.

Rule 83. (1) The purchaser of a prescription drug shall receive, when 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 shall keep and make available for inspection all acquisition and distribution records for prescription drugs and devices, including 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 Non-controlled prescriptions.

Rule 84. (1) A prescriber who issues a prescription for a non-controlled 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, 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 1 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 after the date the prescription was issued.

(5) A pharmacy shall keep the original prescription record for 5 years. Two years after 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 on request.

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

R 338.585 Customized patient medication package.

Rule 85. (1) A pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a CPMP. 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 individual that 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 USP and National Formulary, 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) If 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 are 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 shall record, manually or electronically, the prescription number, dispensing date, and the pharmacist's initials when the prescription is first filled at the pharmacy.

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

(3) If final product verification is completed by a pharmacy technician, under R 338.3665(b), both the initials of the pharmacy technician and delegating pharmacist must be recorded.

(4) 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.

(5) 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 considered 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 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 after 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 when the prescription is first filled and at 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 shall 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 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 after 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 when the prescription is first filled and at 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. Two years after 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. 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 on 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 complies 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 if 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 that term is defined in section 20109 of the code, MCL 333.20109.

(g) An office of a dispensing prescriber, where the device is operated by the dispensing prescriber, not a pharmacy.

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

(i) A location other than subdivisions (a) to (h) of this subrule, where the automated device acts as an extension of a pharmacy. In addition to the requirements in this rule, the automated device must meet the requirements in R 338.588a.

(3) Records and electronic data maintained 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.

(4) Except for devices allowed under R 388.588a(2), policy and procedures for the use of the automated device must include a requirement for pharmacist review of the prescription or medication order before removal of any medication. 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). A pharmacist shall review the orders and authorize any further dispensing within 48 hours.

(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c). A pharmacist shall review the orders and authorize any further dispensing within 48 hours.

(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. A pharmacist shall review the orders and authorize any further dispensing within 48 hours.

(d) The automated device is located in a dispensing prescriber's office to facilitate dispensing by the dispensing prescriber.

(5) 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.

R 338.588a Automated devices in non-inpatient settings.

Rule 88a. (1) A pharmacy that operates an automated device to deliver prescription medication directly to an ultimate user that is not included in R 338.588(2)(a) to (h) shall comply with all of the following requirements:

(a) The automated device may only deliver non-controlled drugs.

(b) The automated device is operated as an extension of a pharmacy, under the control of a pharmacist.

(c) The automated device is secured, lockable, and privacy enabled.

(d) Prescriptions must contain a label that identifies the automated device where the medication was dispensed.

(e) In order for the automated device to be operable, a pharmacist shall be available to provide patient consultation through real-time audio and visual communication. The pharmacist may provide consultation from a remote location.

(f) Before the automated device is put into service, the pharmacy shall notify the department of the location of the automated device on a form provided by the department.

(g) Dispensing activities through the automated device must comply with all recordkeeping, drug utilization review, and patient counseling requirements that are applicable to a pharmacy.

(2) A pharmacy licensee may locate a non-dispensing storage and pick up device inside of the pharmacy that is used for a patient or agent of the patient to pick up prescription medication if the automated device is secured, lockable, and privacy enabled.

(3) If an automated device is used in a dispensing prescriber's office, and the automated device is not affiliated with a pharmacy, the device must be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. 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 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.

R 338.588b Automated devices in medical institutions.

Rule 88b. (1) An automated device used by staff to store medications intended for patient administration in any hospital, county medical care facility, nursing home, hospice, or another skilled nursing facility, as that term is defined in section 20109 of the code, MCL 333.20109, must comply with all of the following:

(a) The automated device must be stocked, maintained, and controlled by a pharmacy that is licensed in this state.

(b) If the stocking of the automated device is performed by non-pharmacist personnel, 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 that complies with R 338.3154.

(c) 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.

(d) 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 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.

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

R 338.589 Professional responsibility; patient counseling; "caregiver" defined.

Rule 89. (1) A pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and devices that are obtained from manufacturers and wholesale distributors licensed under section 17748 of the code, MCL 333.17748, or from other lawful channels of distribution.

(2) A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

(a) The prescription appears to be improperly written.

(b) The prescription is susceptible to more than 1 interpretation.

(c)The pharmacist has reason to believe that the prescription could cause harm to the patient.

(d) The pharmacist has reason to believe that the prescription may be used for other than legitimate medical purposes.

(3) A prescription drug must be dispensed only when the pharmacy is open and under the personal charge of a pharmacist.

(4) To encourage intended, positive patient outcomes, a pharmacist shall communicate to the patient, or the patient's caregiver, necessary and appropriate information regarding safe and effective medication use when a prescription is dispensed. As used in this subrule, "caregiver" means the parent, guardian, or other individual who has assumed responsibility for providing a patient's care. All of the following provisions apply to communicating medication safety and effectiveness information:

(a) The information must be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed or electronic/digital material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.

(b) The information must be provided with each prescription for a drug not previously prescribed for the patient.

(c) If the pharmacist determines it appropriate, the information must be provided with prescription refills.

(d) The information must be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy. This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation. This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.

(5) Pharmacist delegation of acts, tasks, or functions must comply with section 16215 of the code, MCL 333.16215, and be under the personal charge of the delegating pharmacist, except as provided in section 17742b of the code, MCL 333.17742b, R 338.486, and R 338.3665(c). A pharmacist that delegates acts, tasks, or functions to a licensed or unlicensed individual shall do all of the following:

(a) Determine the knowledge and skill required to safely and competently complete the specific act, task, or function to be delegated.

(b) Before delegating an act, task, or function, determine whether the delegate has the necessary knowledge and skills to safely and competently complete the act, task, or function.

(c) Provide written procedures or protocols, or both, to be followed by the delegatee in the performance of the delegated act, task, or function.

(d) Supervise and evaluate the performance of the delegatee.

(e) Provide remediation of the performance of the delegatee, if indicated.

(6) A delegating pharmacist bears the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

(7) A pharmacist may remotely access a pharmacy database as well as any other necessary databases that are routinely accessed to perform their functions. In accessing any database, a pharmacist shall provide adequate security to protect the confidentiality and integrity of a patient's protected health information.

R 338.590 Hospice emergency drug box.

Rule 90. (1) A pharmacy that establishes a medication box exchange program for hospice emergency care services rendered in patients' homes under section 17746 of the code, MCL 333.17746, shall establish drug boxes that comply with this rule. Before providing drug boxes for a hospice emergency care system, the pharmacist in charge shall ensure that the hospice has developed policies and procedures that require all of the following:

(a) Maintenance by the hospice of a drug box exchange log that accounts for the hospice's receipt of the boxes from the pharmacy, assignment of the boxes to registered nurses or physicians' assistants, and return of the boxes to the pharmacy for restocking.

(b) A procedure to ensure that the drug boxes are inspected not less than weekly to determine if they have expired or have been opened.

(c) Procedures for the storage and control of a drug box while it is assigned to, and being used by, the prescriber, a registered nurse, or a physician's assistant.

(d) A procedure for implementing the hospice medical director's responsibility for ensuring that prescriptions for drugs removed from the drug boxes are obtained from an appropriate prescriber.

(2) A pharmacy shall stock drug boxes for a hospice emergency care system in accordance with the policies and procedures developed by the hospice and approved by the hospice medical director.

(3) The drugs contained in each drug box must be listed inside the front cover of the box. Each box must be equipped with only 1 nonreusable, tamper-evident seal or sealing system that is a color that designates that the box has not been opened and several nonreusable, tamper-evident seals or sealing systems that are a different color that designates that the box has been opened.

(4) A drug box must be numbered. A permanent record of all drug boxes must be maintained at the pharmacy.

(5) A label that contains all of the following information must be attached to the drug box so that it is visible from the outside of the box:

(a) The name and address of the pharmacy.

(b) The name and address of the hospice.

(c) The name of the pharmacist who last inspected and restocked the drug box.

(d) The date the drug box was last restocked.

(e) The date the drug box must be returned to the pharmacy for the replacement of expired drugs.

(f) The number of the drug box.

(6) After the drug box has been stocked and labeled, the pharmacist shall seal it with the nonreusable, tamper-evident seal or sealing system that is the color that designates that the box has not been opened.

(7) A drug box must be maintained in a substantially constructed, securely locked storage compartment when not under the direct control of the pharmacist, prescriber, registered nurse, or physician's assistant. The box must be stored under conditions that maintain the stability, integrity, and effectiveness of the drugs. Access to the storage compartment and to the drug box must be limited to individuals who are authorized to stock the drug box or to dispense drugs from the drug box on the order of an appropriate prescriber.

(8) The drug box must remain sealed at all times, except when in use. All drugs removed from the box must be recorded on a medication use form. After completing the form, the physician, registered nurse, or physician's assistant who removed the drug must place the form in the drug box and seal the box with a nonreusable, tamper-evident seal or sealing system that is a color that designates that the box has been opened.

(9) Each drug box under the control of the pharmacy must be examined not less than weekly to ensure that the seal, which designates that the box has not been opened is still intact and the expiration date, has not been exceeded. If the expiration date has been exceeded or the box has been opened, the box must be returned to the pharmacy. The written prescription for all drugs that have been administered from the drug box must accompany the drug box when it is returned to the pharmacy after opening.

(10) The pharmacy shall maintain a permanent record of drug box exchanges on a drug box exchange log. The record must contain all of the following information:

(a) The number of the box.

(b) The name of the hospice to which the box is released.
(c) The date the box is released to the hospice.
(d) The name and signature of the pharmacist who releases the box to the hospice.
(e) The expiration date assigned.
(f) The date the box is returned to the pharmacy for restocking.
(g) The name and signature of the pharmacist who received the box for restocking.
(11) On the return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the appropriate prescriber or medical director of the hospice. The pharmacist shall note that the prescriptions were dispensed from the hospice drug box on the back of the prescriptions. The prescriptions must be filed in the same manner as other prescriptions are maintained at the pharmacy.

R 338.591 Dispensing emergency supply of insulin.
Rule 91. (1) A pharmacist may dispense an emergency supply of insulin to an individual if the pharmacist complies with all of the following:
(a) The requirements in section 17744f of the code, MCL 333.17744f.
(b) An emergency supply of insulin may only be dispensed from a pharmacy with real time access to the qualified prescription for insulin.
(c) Only 1 emergency supply, as that term is defined in MCL 333.17744f, per patient, may be dispensed for each of 3 qualified prescriptions per year.
(2) If the smallest single package of insulin available exceeds a 30-day supply, dispensing the package of insulin that is available complies with this rule and section 17744f of the code, MCL 333.17744f.

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