LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

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

R 338.471 Rescinded.

History: 1979 AC; 2020 MR 24, Eff. Dec 22, 2020.

R 338.471a Rescinded.

History: 1980 AACS; 1986 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.471b Rescinded.

History: 2017 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.472 Rescinded.

History: 1979 AC; 1980 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.473 Rescinded.

History: 1979 AC; 1980 AACS; 1990 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.473a Rescinded.

History: 1979 AC; 1980 AACS; 1986 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.473b Rescinded.

History: 1979 AC; 1980 AACS; 1986 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.473c Rescinded.

History: 1980 AACS; 1986 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.473d Rescinded.

History: 1986 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.474 Rescinded.

History: 1979 AC; 1980 AACS; 1988 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.474a Rescinded.

History: 1983 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.475 Rescinded.

History: 1979 AC; 1980 AACS; 1990 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.476 Rescinded.

History: 1979 AC; 1980 AACS; 1998-2000 AACS.

R 338.477 Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.477a Rescinded.

History: 1979 AC; 2020 MR 24, Eff. Dec 22, 2020.

R 338.477b Rescinded.

History: 1980 AACS; 1986 AACS; 1998-2000 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.477c Rescinded.

History: 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.477d Rescinded.

History: 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.478 Rescinded.

History: 1979 AC; 2020 MR 24, Eff. Dec 22, 2020.

R 338.479 Rescinded.

History: 1979 AC; 1980 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.479a Rescinded.

History: 1979 AC; 1980 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.479b Rescinded.

History: 1998-2000 AACS; 2000 AACS; 2007 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.479c Rescinded.

History: 1998-2000 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.480 Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.480a Rescinded.

History: 1992 AACS; 1998-2000 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.481 Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.482 Rescinded.

History: 1979 AC; 1980 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.483 Rescinded.

History: 1979 AC; 1992 AACS.

R 338.484 Rescinded.

History: 1979 AC.

ADMINISTRATIVE HEARINGS

R 338.485 - R 338.485y Rescinded.

History: 1979 AC; 1980 AACS.

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 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 shall be 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 administration of first doses. If the interpretation and review will cause a medically unacceptable delay, then 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, such as 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) Delegating the stocking of an automated device. 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.

(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 kept within the medical institution.

(i) Providing educational programs regarding medications and their safe use.

(j) Providing a method 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 method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist must be available on an on-call basis. Only a limited number of medications that are packaged in units of use must be available. The medications must be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication must be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication must be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number. A written order and a proof of removal and use document must be obtained for each medication unit removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) Upon 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 at least 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 which are designed to be tamper-evident and which show no evidence that tampering has occurred may be returned to stock. Medications that leave the medical institution or its legal affiliates may not be returned to stock for dispensing.

(8) The licensed pharmacist who directs pharmacy services in the medical institution shall make the policies, procedures, and written reports required by this rule available to the board, upon request.

History: 1979 AC; 1980 AACS; 1998-2000 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.487 Rescinded.

History: 1979 AC.

R 338.488 Rescinded.

History: 1979 AC; 1982 AACS; 1988 AACS; 1990 AACS; 2013 AACS.

R 338.489 Rescinded.

History: 1979 AC; 1980 AACS; 2007 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.490 Rescinded.

History: 1979 AC; 1990 AACS; 1998-2000 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.491 Rescinded.

History: 1979 AC.

R 338.492 Rescinded.

History: 1979 AC.

R 338.493a Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.493b Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 2013 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.493c Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.493d Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.493e Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.493f Rescinded.

History: 1979 AC; 1980 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.493g Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 2020 MR 24, Eff. Dec 22, 2020.

R 338.493h Rescinded.

History: 1979 AC; 1980 AACS.

R 338.494 Rescinded.

History: 1979 AC; 1982 AACS; 1988 AACS.

R 338.495 Rescinded.

History: 1979 AC; 1988 AACS; 1998-2000 AACS.

R 338.496 Rescinded.

History: 1979 AC; 1998-2000 AACS.

R 338.497 Rescinded.

History: 1981 AACS; 2013 AACS; 2014 AACS.

R 338.500 Rescinded.

History: 1995 AACS; 2020 MR 24, Eff. Dec 22, 2020.

PART 1. GENERAL PROVISIONS

R 338.501 Definitions.

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

(a) "Approved education program" means a school of pharmacy that is accredited by or has candidate status by the Accreditation Council for Pharmacy Education.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) "Practical experience" means professional and clinical instruction in, but not limited to, all of the following areas:

(i) Pharmacy administration and management.

(ii) Drug distribution, use, and control.

(iii) Legal requirements.

(iv) Providing health information services and advising patients.

(v) Pharmacist's ethical and professional responsibilities.

(vi) Drug and product information.

(vii) Evaluating drug therapies and preventing or correcting drug-related issues.

(j) "Virtual manufacturer" means a person who engages in the manufacture of prescription drugs or devices and meets all of the following:

(i) Owns either of the following:

(A) The new prescription drug application or abbreviated new prescription drug application number.

(B) The unique device identification number, as available, for a prescription device.

(ii) Contracts with a contract manufacturing organization for the physical manufacture of the drugs or devices.

(iii) Is not involved in the physical manufacture of the drugs or devices.

(iv) At no time takes physical possession of or stores the drugs or devices.

(v) Sells or offers for sale to other persons, for resale, compounding, or dispensing of, drugs or devices, salable on prescription only.

(2) The terms defined in the code have the same meaning when used in these rules.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.503 Prescription drugs and devices; return or exchange for resale prohibited.

Rule 3. (1) Prescription drugs or devices that have been dispensed and have left the control of the pharmacist must not be returned or exchanged for resale.

(2) This rule does not apply to any of the following:

(a) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail, as provided in section 17766d of the code, MCL 333.17766d.

(b) A pharmacy or charitable clinic that participates in the program for the utilization of unused prescription drugs, as provided in section 17775 of the code, MCL 333.17775.

(c) A pharmacy or health facility that participates in the cancer drug repository program, as provided in section 17780 of the code, MCL 333.17780.

(d) Drugs returned when the wrong medication was dispensed to the patient or in the instance of a drug recall. Subject to R 338.486(7), in no instance may returned drugs be reused or returned to active stock.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.505 Inspection of applicants and licensees.

Rule 5. (1) The board, board inspector, board agent, or approved entity pursuant to R 338.532, may enter at reasonable times, any building, place, or facility that is owned or controlled by any applicant for, or holder of, a license to make an inspection to enable the board to determine if the applicant possesses the qualifications and competence for the license sought or to determine whether a license holder is and has been complying with the code and rules. The inspection must concern only matters relevant to the applicant's or license holder's practice of pharmacy, manufacturing, and wholesale distributing of drugs and devices saleable by prescription only.

(2) The inspection must not extend to any of the following information:

(a) Financial data.

(b) Sales data other than shipment data.

(c) Pricing data.

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

(e) Research data.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

PART 2. PHARMACIST LICENSES

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

Rule 11. (1) Pursuant to section 16148 of the code, MCL 333.16148, an individual seeking licensure or who is licensed shall complete 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 health care settings.

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

(iv) 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 reviewed journal, health care 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 a sample of individuals and request documentation of proof of completion of training. If audited by the department, an 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 an individual. The certification statement must include the individual's name and either of the following:

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

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

(3) Pursuant to section 16148 of the code, MCL 333.16148, the requirements specified in subrule (1) of this rule apply for license renewals beginning January 1, 2020 and for initial licenses issued after November 13, 2022.

History: 2020 MR 24, Eff. Dec 22, 2020.

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

Rule 13. (1) An applicant for an educational limited license shall submit to the department a completed application on a form provided by the department with the

requisite fee. In addition to satisfying the requirements of sections 16174 and 17737 of the code, MCL 333.16174 and MCL 333.17737, the applicant shall establish either of the following:

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

(b) That he or she has successfully passed the foreign pharmacy graduate equivalency examination administered by the national association of boards of pharmacy (NABP) Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056, https://nabp.pharmacy/programs/fpgec/ .

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

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

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

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.515 Internship requirements.

Rule 15. (1) An internship must be a minimum of 1,600 hours, 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. "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 person previously approved by the board shall verify the hours.

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

(3) If an internship is not completed through an approved educational program or under the personal charge of a preceptor licensed in this state, the individual shall petition the board for approval of hours.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.517 Preceptor license and responsibilities.

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

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

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

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

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

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

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

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

(d) Annually submit training affidavits and, upon completion of the training, provide comments regarding the ability of the intern to practice pharmacy without supervision on a form provided by the department.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.519 Examinations adoption; passing scores; reexamination.

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

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

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

(4) If an applicant for licensure fails to pass either of these examinations, within 3 attempts, he or she shall provide the board, after the third attempt and prior to retesting, certification from an approved education program certifying that he or she satisfactorily completed courses that provide a thorough review of the area or areas that he or she failed in the most recent examination.

(5) An applicant who fails to pass the NAPLEX shall wait at least 45 days to retest or comply with the current waiting period established by NABP, whichever is later. An

applicant who has not achieved a passing score on the NAPLEX shall not take the NAPLEX more than 3 times in a 12-month period.

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.521 Pharmacist licensure by examination.

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

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

(a) Earned either of the following:

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

(ii) A foreign pharmacy graduate examination committee certificate administered by the NABP.

(b) Successfully passed the MPJE and the NAPLEX.

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

(3) An applicant's license shall be verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.523 Pharmacist license by endorsement; requirements.

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

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

(a) Establish that the he or she is currently licensed in another state or he or she successfully passed the foreign pharmacy graduate examination administered by NABP and was initially licensed by examination in another state.

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

(c) Have his or her license verified by the licensing agency of any state of the United States in which the applicant holds or has ever held a license to practice pharmacy. This includes, but is not limited to, showing proof of any disciplinary action taken or pending against the applicant.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.525 Relicensure of a pharmacist license; requirements.

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

For a pharmacist who has let his or her license lapse and who is not currently licensed in another state:	License lapsed 0-3 years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite fee.	X	X	X
(b) Good moral character: establish that he or she is of good moral character as defined under sections 1 to 7 of 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints: submit fingerprints as required under section 16174(3) of the code, MCL 333.16174(3).		X	X
(d) Continuing education: submit proof of having completed 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately preceding the date of application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years from the date of the application to complete the deficient hours. The application will be held and the license will not be issued until the continuing education requirements have been met.	X	X	X

(e) Pass MPJE: retake and pass the MPJE as provided in R 338.519.		X	X
(f) Submit proof of having completed both a 1-time training in identifying victims of human trafficking as required in R 338.511 and a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.	X	X	X
(g) Practical experience: complete 200 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of applying for relicensure.		X	
(h) Practical experience: complete 400 hours of practical experience under the personal charge of a currently licensed Michigan pharmacist in or outside of Michigan, within 6 months of applying for relicensure.			X
(i) Examination: pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X
(j) Verification: submit verification from the licensing agency of all other states of the United States in which the applicant has ever held a license to practice pharmacy. Verification must include the record of any disciplinary action taken or pending against the applicant.	X	X	X

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

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

(4) For a pharmacist who has let his or her pharmacist license lapse, but who holds a current and valid pharmacist license in another state:	License lapsed 0-3 Years	License lapsed more than 3 years, but less than 8 years	License lapsed 8 or more years
(a) Application and fee: submit to the department a completed application on a form provided by the department, with the requisite	X	X	X

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

History: 2020 MR 24, Eff. Dec 22, 2020.

PART 3. PHARMACY LICENSES

R 338.531 Pharmacy license; applications; requirements.

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

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

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

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

(c) Proof of registration or licensure from every state or province where the pharmacy is currently licensed or has ever held a license or registration.

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

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

(f) A completed self-inspection form.

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

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.532 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 not be 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 from 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 of 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.

History: 2020 MR 24, Eff. Dec 22, 2020.

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

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

(2) The standards adopted by reference in subrule (1) of this rule are available at cost at http://www.usp.org/compounding, or at cost from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.

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

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

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

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

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

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

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

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

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

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

(i) Required drug and ingredient information.

(ii) Facility identification.

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.534 Inspections.

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

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

(3) An applicant for licensure of a pharmacy that will provide sterile compounded pharmaceuticals shall have all of the following:

(a) An onsite physical inspection conducted by any of the following:

(i) The department.

(ii) The national association of boards of pharmacy verified pharmacy program (NABP-VPP).

(iii) An accrediting organization according to R 338.532.

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.535 Discontinuing sterile compounding services; requirements to resume sterile compounding services.

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

(2) A pharmacy shall not resume providing sterile compounding services in this state until the pharmacy is approved by the department and is accredited or an organization satisfying the requirements of R 338.532(1) verifies that the pharmacy is USP compliant.

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.536 Housing of a pharmacy.

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.537 Professional and technical equipment and supplies.

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

(a) Drawers, shelves, and storage cabinets.

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.538 Closing pharmacy.

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

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.539 Relicensure.

Rule 39. (1) An applicant for relicensure of a pharmacy license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) A pharmacy that has an expired license shall satisfy the requirements of R 338.531 to be relicensed.

History: 2020 MR 24, Eff. Dec 22, 2020.

PART 4. MANUFACTURER LICENSE

R 338.551 Manufacturer license; application.

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

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

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

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

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

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

(e) A completed compliance checklist for manufacturers.

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

(g) Unless exempt under section 17748(2) of the code, MCL 333.17748(2), the name and license number of the pharmacist designated as the pharmacist in charge (PIC).

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.553 Persons to whom prescription drugs or devices may be sold.

Rule 53. A manufacturer may only supply, distribute, sell, barter, or otherwise transfer prescription drugs or devices to persons who are licensed by the board to distribute, prescribe, or dispense prescription drugs or devices in or outside this state.

History: 2020 MR 24, Eff. Dec 22, 2020.

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

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

(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, MI 48909.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.557 Closure of a manufacturer.

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

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of non-controlled substances.

(d) The disposition of records and prescription files.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.559 Relicensure.

Rule 59. (1) An applicant for relicensure of a manufacturer license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) A manufacturer that has an expired license shall satisfy the requirements of R 338.551 in order to be relicensed.

History: 2020 MR 24, Eff. Dec 22, 2020.

PART 5. WHOLESALE DISTRIBUTOR LICENSE

R 338.561 Pharmacy as wholesale distributor; licensure.

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

(a) The distribution of a drug among hospitals or other health care entities which are under common control.

(b) Intracompany distribution of any drug between members of an affiliate, defined pursuant to section 360eee(1) of the Federal Food, Drug, and Cosmetic Act, 21 USC section 360eee(1), or within a manufacturer.

(c) Distribution of a drug by a charitable organization to a nonprofit affiliate of the organization, defined pursuant to section 360eee(1) of the Federal Food, Drug, and Cosmetic Act, 21 USC section 360eee(1).

(d) Distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, 42 USC 247d.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.563 Wholesale distributor; application for licensure; requirements.

Rule 63. (1) An applicant for a wholesale distributor 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 provide all of the following information:

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

(b) Proof of registration or licensure from every state where the applicant currently holds or has ever held a license or registration.

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

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

(e) A completed compliance checklist.

(f) A list or catalog of all drug products and devices to be distributed.

(g) A copy of the FDA certification for the site to be licensed, if the applicant is distributing biologicals.

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

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

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

(I) A high school diploma.

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

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

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

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

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

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

(III) Knowledge and understanding of quality control systems.

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

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

(C) Experience equal to either of the following:

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.565 Persons to whom prescription drugs and devices may be sold.

Rule 65 A wholesale distributor of prescription drugs or devices may supply, distribute, sell, barter, or otherwise transfer prescription drugs or devices only to persons who are licensed by the board to distribute, prescribe, or dispense prescriptions drugs or devices in or outside this state.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.567 Wholesale distributor practices; control of prescription drugs or devices; inspections.

Rule 67. (1) A wholesale distributor that does not physically touch prescription drugs or devices shall file an affidavit with the department signed by the PIC or facility manager attesting to this fact.

(2) A wholesale distributor that previously filed an affidavit under subrule (1) of this rule shall not obtain custody and control of drugs or devices until both of the following have occurred:

(a) The licensee provides written notification to the department of physical custody.

(b) The department conducts an inspection of the premises.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.569 Wholesale distributor recordkeeping and policy requirements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) The records described in this rule must be maintained for a minimum of 2 years after the disposition of the prescription drugs or devices.

History: 2020 MR 24, Eff. Dec 22, 2020.

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 for 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 have been 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 will provide protection against theft and diversion. When 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 pursuant to the label requirements or 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.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.573 Examination of materials; returned, damaged and outdated prescription drugs or devices.

Rule 73. (1) A wholesale distributor shall comply with both of the following provisions that pertain to the examination of materials:

(a) Each outside shipping container must be visually examined upon receipt for the identity of the prescription drug or devices and to prevent the acceptance of contaminated prescription drugs or devices or prescription drugs or devices otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment must be visually inspected for identity of the prescription drug products and to ensure that prescription drugs or devices that have been damaged in storage or held under conditions that are inconsistent with USP compendium standards are not delivered.

(2) All of the following provisions apply to returned, damaged, and outdated prescription drugs or devices:

(a) Prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, must be quarantined and physically separated from other prescription drugs or devices until they are destroyed or returned to the supplier.

(b) Any immediate or sealed outer or sealed secondary containers of any prescription drugs or devices that have been opened or used must be identified as such and the drugs or devices must be quarantined and physically separated from other prescription drugs or devices until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(3) The recordkeeping requirements of R 338.569 must be followed.

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.575 Closing a wholesale distributor.

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

(a) The effective date of closing.

(b) The disposition of controlled substances.

(c) The disposition of noncontrolled substances.

(d) The disposition of records and prescription files.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.577 Relicensure.

Rule 77. (1) An applicant for relicensure of a wholesale distributor license shall submit to the department a completed application on a form provided by the department with the requisite fee.

(2) An applicant for relicensure of a wholesale distributor license that has expired must satisfy the requirements of R 338.563 in order to be relicensed.

PART 6. PRACTICE OF PHARMACY

R 338.582 Prescription drug labeling and dispensing.

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

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

(a) Pharmacy name and address.

(b) Prescription number.

(c) Patient's name.

(d) Date the prescription was most recently dispensed.

(e) Prescriber's name.

(f) Directions for use.

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

(h) The quantity dispensed, if applicable.

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

(3) If a drug is dispensed that is not the brand prescribed, the pharmacy shall notify the purchaser and the prescription label must indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a

brand name, the prescription label must indicate the name of the brand prescribed followed by the generic name of the drug dispensed. This subrule does not apply if the prescriber indicates "do not label."

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.583 Prescription drug receipts.

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

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

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

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

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription.

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

(h) The name of the prescriber.

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

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

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.584 Noncontrolled prescriptions.

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

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

(b) The prescriber's printed name and address.

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

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

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

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

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

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

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

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

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

(ii) Technical non-repudiation.

(iii) Content integrity.

(iv) Confidentiality.

(b) An electronic signature as defined in R 338.501(1)(g). An electronic signature is valid when it is used to sign a noncontrolled prescription.

(c) Appropriate security measures to invalidate a prescription if either the electronic signature or prescription record to which it is attached or logically associated is altered or compromised following transmission by the prescriber. The electronic prescription may be reformatted to comply with industry standards provided that no data is added, deleted, or changed.

(6) The electronic prescription must meet all requirements of the HIPAA.

(7) The electronic prescription must permit the prescriber to instruct the pharmacist to dispense a brand name drug product provided that the prescription includes both of the following:

(i) The indication that no substitute is allowed, such as "dispense as written" or "DAW."

(ii) The indication that no substitute is allowed and that it is a unique element in the prescription.

(8) If the prescription is transmitted electronically, the prescriber shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form. The electronic prescription must identify the name of the pharmacy intended to receive the transmission, and must include the information identified in subrule (1) of this rule.

(9) The electronic prescription must be preserved by a licensee or dispensing prescriber for not less than 5 years. A paper version of the electronic prescription must be made available to an authorized agent of the board upon request. A secured copy must be retained for a minimum of 1 year by the transaction service vendor for record-keeping purposes and must be shared only with the parties involved in the transaction except as otherwise permitted by state or federal law.

(10) An electronic signature that meets the requirements of this rule has the full force and effect of a handwritten signature on a paper-based written prescription.

(11) A pharmacy shall keep the original prescription record for 5 years. After 3 years, a pharmacy may make an electronic duplicate of the original paper prescription, which will become the original prescription. A pharmacy shall present a paper copy of the electronic duplicate of the prescription to an authorized agent of the board upon request.

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.585 Customized patient medication package.

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

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

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

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

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

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

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

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

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

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

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

(b) A CPMP must be accompanied by any mandated patient information required under federal law. Alternatively, required medication information may be incorporated by

the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

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

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

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

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

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

(iv) The drug products require special packaging.

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

(f) Medications that have been dispensed in CPMP packaging shall 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.

History: 2020 MR 24, Eff. Dec 22, 2020.

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

Rule 86. (1) A prescription must be numbered, dated, and initialed or electronically initialed by the pharmacist who performs the final verification prior to dispensing at the time of the first filling at the pharmacy.

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

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

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

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

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

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

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

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

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

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

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

(v) The number of refills authorized.

(vi) The "dispense as written" instructions, if indicated.

(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed, and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.

(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(c) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription

or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and must initial the record each time a prescription is filled or refilled.

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

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

(a) All information that is pertinent to a prescription must be entered on the record, including all of the following information:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

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

(v) The number of refills authorized.

(vi) Whether the drug must be dispensed as written.

(vii) The name, strength, dosage form, quantity, and name of the manufacturer of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed must be indicated.

(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(b) Prescription entries must be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The pharmacy shall preserve the records on-site for 5 years. The records are subject to inspection by the board or its agents. A procedure must be established to facilitate inspections.

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

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

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

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

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.588 Automated devices.

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

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

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

(b) A hospital.

(c) A county medical care facility.

(d) A hospice.

(e) A nursing home.

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

(g) An office of a dispensing prescriber.

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

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

(4) If an automated device is used in a dispensing prescriber's office, the device must be used only to dispense medications to the dispensing prescriber's patients and only

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

(a) If a dispensing prescriber delegates the stocking of the automated device, then technologies must be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that complies with R 338.3154.

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

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

(i) Manufacturer name and model.

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

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

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

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

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

(b) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility must be maintained by the pharmacy for review by an

agent of the board. The documentation must include at least all of the following information:

(i) Name and address of the pharmacy responsible for the operation of the automated device.

(ii) Name and address of the facility where the automated device is located.

(iii) Manufacturer name and model number.

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

(v) Policy and procedures for system operation that address at a minimum all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

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

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

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

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

(b) Records must be maintained for 5 years by the pharmacy or dispensing prescriber and must be retrievable on demand for review by an agent of the board. The records must include all of the following information:

(i) The unique identifier of the automated device accessed.

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

(iii) The type of transaction.

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

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

(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the automated device.

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

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

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

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

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

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

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

History: 2020 MR 24, Eff. Dec 22, 2020.

R 338.589 Professional responsibility; "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 will 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 at the time 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 deems 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 shall be in compliance with section 16215 of the code, MCL 333.16215, and under the personal charge of the delegating pharmacist, except as provided in R 338.486. A pharmacist who delegates acts, tasks, or functions to a licensed or unlicensed person 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, make a determination that 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 shall bear the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

History: 2020 MR 24, Eff. Dec 22, 2020.

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 pursuant to the provisions of section 17746 of the code, MCL 333.17746, shall establish drug boxes that are in compliance 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 at least 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 which is a color that designates that the box has not been opened and several nonreusable, tamper-evident seals or sealing systems which 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 on which 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 which is the color that designates that the box has not been opened.

(7) A drug box must be kept 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 will 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 which is a color that designates that the box has been opened.

(9) Each drug box under the control of the pharmacy must be examined at least 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) Upon 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.

History: 2020 MR 24, Eff. Dec 22, 2020.