MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING MINUTES
October 3, 2025

The Michigan Board of Pharmacy Rules Committee Work Group met on October 3, 2025. The meeting was held via Zoom.

CALL TO ORDER

Jennifer Shaltry, JD, Departmental Specialist, called the meeting to order at 10:03 a.m.

ATTENDANCE

Members Present:
Rony Foumia, R. Ph.
Grace Sesi, PharmD
Michael Sleiman, PharmD
Sandra Taylor, R.Ph.

Staff Present:
Jennifer Shaltry, JD, Departmental Specialist, Boards and Committees Section
Kim Smith, Board Support Technician, Boards and Committees Section
Christina Koehler, Manager, Licensing Section
Shermita Mitchell, Manager, Pharmacy and Drug Monitoring Section
Brian Hoot, Department Analyst, Michigan Automated Prescription System
Amber Daniels, Department Specialist, Michigan Automated Prescription System

Public Present:
Eric Roath, Michigan Pharmacists Association
Lindsay Kunkle, Kroger Health
Tonino Michienzi
Maria Young, University Pharmacy
Brittany Stewart, Wayne State University
Leang Mey Tao, Michigan Pharmacists Association
Sarah Cronin
Ilisa Bernstein
Michelle Aytay
Susan Davis, Wayne State University

Joseph Paul Javier
Jessica Cole
Christopher Jones
Scott Young
Jennifer Falkenrath
Christina Respondek
Krupa

RULES DISCUSSION

PHARMACY – PHARMACIST CONTINUING EDUCATION

The rules committee considered written comments from the following:

Suzanne Williams, Pacific Medical Training

After reviewing the comment, the committee agreed to add language authorizing joint providership to R 338.3044 Acceptable continuing education for licensees.

PHARMACY - GENERAL RULES

Shaltry explained there were a couple comments received on closed rules and that those would not be discussed.

The rules committee considered written comments from the following:

- Susan Davis, PharmD, Assoc. Dean for Pharmacy, Wayne State University
- Krupa, Pharm D
- Joseph Paul Pacis Javier, PharmD
- Michelle Kelly (Sahr) PharmD, BCACP, FMPA Associate Professor, College of Pharmacy, Ferris State University
- Michigan Pharmacists Association
- Lynette Moser, PharmD Chair & Clinical Associate Professor, Wayne State University
- Chris Munden, RPh, President, Hemmingsen Drug Store
- Obioma Opara, PharmD, Pharmacy Resident, Sinai-Grace/DMC
- Sally Rafie, PharmD, BCPS, APh, FCCP, FCPhA, Founder, Birth Control Pharmacist
- Arian Shaska, Trinity Health Pharmacy Intern, PharmD Candidate
- Brittany Stewart, RD, PharmD, Clinical Associate Professor, Wayne State University
- Hsin Wang, MD, FACOG, Chief of Department of Obstetrics & Gynecology, Huron Valley Sinai Hospital

- Wayne County Department of Health, Human & Veterans Services
- Micaiah Whitaker, PharmD Candidate, Pharmacist Intern, CVS
- Maria Young, RPh, University Pharmacy

R 338.507 Telehealth.

After reviewing the comments, the committee agreed to add, “health professional or agent of the health professional” in place of “health professional”.

R 338.523 Pharmacist license by endorsement; requirements.

After reviewing the comments, the committee agreed that the requested changes could not be made because they conflict with the Michigan Public Health Code.

R 338.531a Remote pharmacy waiver from mileage requirement.

After reviewing the comments, the committee agreed that a change to this rule was not necessary.

R 338.581 Ordering and administration of qualified immunizing agent; training program.

Foumia shared he did not want to put barriers on his colleagues and the board agreed.

Sesi shared that “qualified immunizing agent” was defined in statute and to avoid being redundant, that is why it was not defined in the rules. The committee agreed to not define “qualified immunizing agent” in the rule.

The committee agreed to update the last sentence to include, “a pharmacist shall successfully complete a training course on the administration of vaccines that is provided by an entity **or course** accredited by the ACPE.

R 338.581a Ordering and administration of qualified laboratory test; dispensing drug without prescription based on test result; training program.

Foumia suggested leaving the employer-based training as an option to fulfill the training requirement.

Discussion held.

The committee agreed to keep employer-based training as a way to meet the training requirement.

The committee agreed that a definition for “qualified laboratory test” was not needed in the rule because the definition was in the Michigan Public Health Code.

Susan Davis thanked the committee for the opportunity to speak.

R 338.581b Pharmacist prescribing a contraceptive; board-approved training program required.

The rule states: Before issuing a prescription for a contraceptive under section 17744g of the code, MCL 333.17744g, a pharmacist shall successfully complete a training course on prescribing and dispensing contraceptives that is provided by an entity accredited by the ACPE.

> The committee agreed to add, “a pharmacist shall successfully complete a training course on prescribing and dispensing contraceptives that is provided by an entity **or course** accredited by the ACPE” to Rule 81b.

Rule 338.581c Prescribing and dispensing a contraceptive; standard procedure.

After reviewing the comments received, the committee agreed to remove any referral requirements from the rule that are not mandated by statute. Shaltry shared that discussion will continue with the full board at the next meeting.

Subrule 328.81c(b)(iv): After reviewing a comment received, “written” cannot be removed from the rule due to statute. Shaltry explained that an electronic record was considered a written record in many other contexts. The committee agreed to add written “**or electronic**” to the rule.

Subrule 328.81c(b)(v): The committee agreed to adopt the MPA’s suggestion to simplify the language concerning dispensing the contraceptive as soon as practicable or transmitting the prescription to another pharmacy.

R 338.581d Self-screening risk assessment tool.

Eric Roath, from the Michigan Pharmacists Association, shared language to be adopted in place of Appendix A

Foumia felt the self-screening risk assessment tool should be left general and have minimum requirements to make it easier for the providers.

Discussion was held.

Sesi stated that the questions in Appendix A align with the CDC criteria.

After reviewing the comments received, the committee agreed to leave the self-screening risk assessment tool in the rules and made no changes.

Shaltry shared that the Board of Pharmacy will review the suggested changes at the next meeting on October 15, 2025, and from there, the rules will be sent to the Joint Committee on Administrative Rules.

ADJOURNMENT

Shaltry adjourned the meeting at 11:42am

Prepared by:
Kim Smith, Board Support Technician October 8, 2025
Bureau of Professional Licensing

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PHARMACIST CONTINUING EDUCATION

Filed with the secretary of state on

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

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16145, 16148, 16184, 16201, 16204, 16205, 17731, and 17767 of the public health code, 1978 PA 368, MCL 333.16145, 333.16148, 333.16184, 333.16201, 333.16204, 333.16205, 333.17731, and 333.17767, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.3041, R 338.3042, and R 338.3044 of the Michigan Administrative Code are amended, as follows:

R 338.3041 Definitions.

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

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

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

(c) "CCAPP" means the Canadian Council for Accreditation of Pharmacy Programs.

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

(~~c~~**e**) "Department" means the department of licensing and regulatory affairs.

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

R 338.3042 License renewals; continuing education requirements; applicability.

Rule 2. (1) These rules apply to applications for renewal of a pharmacist's license and a special retired volunteer pharmacist's license under sections 16201 and 16184 of the code, MCL 333.16201 and 333.16184. A licensee seeking renewal shall comply with all of the following:

(a) Submit a completed application on a form provided by the department, together with the requisite fee.

(b) ~~Beginning with renewals on January 1, 2020, an applicant for license renewal shall have completed~~ **Complete** a 1-time training identifying victims of human trafficking as required in R 338.511 and section 16148 of the code, MCL 333.16148.

(c) ~~An applicant for license renewal, who also applies for a controlled substance license, shall have completed~~ **Complete** a ~~1-time~~ training in opioids and other controlled substances awareness as required in R 338.3135, **if also applying for a controlled substance license**.

(d) The continuing education requirements apply to an applicant ~~for license renewal,~~ who has been licensed for the 2-year period immediately preceding the end of the license cycle.

(e) ~~An applicant for license renewal shall furnish the board with~~ **Submit to the board** satisfactory evidence that the applicant completed not less than 30 hours of continuing education approved by the board, under R 338.3043 and R 338.3044, during the license cycle before the application for renewal. Continuing education that is earned during the 60-day grace period may be included up to the date the application for renewal is filed. An applicant for license renewal shall complete all of the following continuing education requirements:

(i) At least 1 hour of the 30 required hours of continuing education in pharmacy ethics and pharmacy law, which may be completed in 1 or more courses.

(ii) At least 10 hours of the 30 required hours of continuing education must be live, synchronous, courses or programs, in-person or virtual, that provide for the opportunity of direct interaction between faculty and participants, including**,** but not limited to, lectures, symposia, live teleconferences, and workshops. ~~Accreditation Council for Pharmacy Education (~~ACPE~~)~~ courses designated as live meet this requirement.

(iii) At least 1 hour of the 30 required hours of continuing education in pain and symptom management, as required under section 16204(2) of the code, MCL 333.16204. Continuing education in pain and symptom management includes, but is not limited to, courses in behavior management, psychology of pain, pharmacology, behavior modification, stress management, clinical applications, and drug interventions as they relate to professional practice.

(iv) Not more than 12 hours of continuing education during a 24-hour period.

(2) Except for the 1-time training in human trafficking, the ~~1-time~~ training in opioid and controlled substances awareness, and the implicit bias training, which may be used to comply with both the training requirement and the continuing education requirement in the same renewal period, an applicant for license renewal may not earn continuing education credit for a program or activity that is identical to a program or activity an applicant has already earned credit for during that renewal period.

(3) Submission of an application for renewal constitutes the applicant's certification of compliance with the requirements of this rule. An applicant shall retain documentation of meeting the requirements of this rule for a period of 4 years from the date of applying for license renewal. The board may require an applicant to submit evidence to demonstrate compliance with this rule. Failure to comply with this rule is a violation of section 16221(h) of the code, MCL 333.16221.

(4) A request for a waiver under section 16205 of the code, MCL 333.16205, must be received by the department **for the board's consideration not less than 30 days before the last regularly scheduled board meeting** before the expiration date of the license.

The public notice for the board meetings can be found at: https://www.michigan.gov/lara/bureau-list/bpl/health/hp-lic-health-prof/pharmacy.

~~(5) Except as otherwise stated, this rule takes effect upon promulgation of the rules.~~

R 338.3044 Acceptable continuing education for licensees.

Rule 4. The board shall consider all of the following as acceptable continuing education:

ACCEPTABLE CONTINUING EDUCATION ACTIVITIES		
	Type of Activity	Number of Hours Earned/Maximum Hours
(a)	Completion of an approved continuing education course or program related to the practice of pharmacy. A continuing education course or program is approved, regardless of the format in which it is offered, if it is approved or offered for continuing education credit by any of the following: A pharmacy program accredited by the ACPE or the ~~Canadian Council for Accreditation of Pharmacy Programs (~~CCAPP~~)~~. A continuing education sponsoring organization, institution, or individual approved by the ACPE. Another state board of pharmacy. **A continuing education sponsoring organization, institution, or individual approved by a non-pharmacy healthcare board or accreditation entity.** If audited, a licensee shall submit a copy of a letter or certificate of completion showing the licensee's name, number of hours earned, sponsor name or the name of the organization that approved the program or activity for continuing education credit, and the date on which the program was held, or activity completed.	The number of hours earned ~~will be~~ **is** the number of hours approved by the sponsor or the approving organization. If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation may be earned. **There is no** ~~No~~ limitation on the number of hours earned**, except that a maximum of 5 hours may be earned per renewal period for activities offered by a continuing education sponsoring organization, institution, or individual approved by a non-pharmacy healthcare board or accreditation entity**.
(b)	Completion of postgraduate pharmacy practice or administration courses offered for credit in a pharmacy school accredited by the ACPE or the CCAPP. If audited, a licensee shall submit an official transcript that reflects completion of	Twelve hours of continuing education ~~will be~~ **is** earned for each academic quarter credit earned and 18 hours ~~will be~~ **is** earned for each academic semester credit earned.

	the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.	**There is no** ~~No~~ limitation on the number of hours earned.
(c)	Participation in a home study program offered through an ACPE-approved provider or other instructional approaches that include an evaluation component including, but not limited to, on-line continuing education programs and journal articles. If audited, a licensee shall submit an affidavit attesting to the number of hours the licensee spent participating in the home study program that includes a description of the activity.	One hour ~~will be~~ **is** earned for each hour devoted to a home study program. A maximum of 20 hours may be earned per renewal period.
(d)	Participation as a preceptor for at least 1 pharmacy intern. A preceptorship shall be for a minimum of 120 hours in person and have a 1 intern - to - 1 preceptor ratio. This may involve multiple preceptor relationships at different times. If audited, a licensee shall submit written documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.	Five hours of continuing education **is** ~~may be~~ earned for a minimum of 120 hours in person of preceptorship in each renewal period. A maximum of 5 hours may be earned in each renewal period.
(e)	Renewal of a pharmacy license held in another state that requires continuing education for license renewal that is substantially equivalent in subject matter and total amount of required hours to that required in these rules if the licensee resides and practices in another state. If audited, a licensee shall submit proof of current licensure in another state and a copy of a letter or certificate of completion showing all of the following: The licensee's name. Number of hours earned. The sponsor's name or the name of the organization that approved the program or activity for continuing education credit.	Thirty hours ~~will be~~ **is** earned. A maximum of 30 hours may be earned in each renewal period.

	The date on which the program was held, or the activity was completed.	
(f)	Initial publication of an article or a chapter related to the practice of pharmacy in either of the following: A pharmacy textbook. A ~~peer reviewed~~ **peer-reviewed** journal. If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.	Ten hours ~~will be~~ **is** earned per publication. A maximum of 10 hours may be earned in each renewal period.
(g)	Successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties ~~(BPS)~~. If audited, a licensee shall submit proof of a passing score on the examination.	Ten hours ~~may be~~ **is** earned in the year in which the licensee achieves a passing score. A maximum of 20 hours may be earned in each renewal period. Credit ~~will~~ **is not** ~~be~~ given for repeating the same examination twice in a renewal period.
(h)	Presentation of a continuing education program approved by the board under R 338.3043 or subdivision (a) of this rule that is not a part of the licensee's regular job description. If audited, a licensee shall submit a copy of the curriculum and a letter from the program sponsor verifying the length and date of the presentation.	Two hours **is earned** for every 50 minutes devoted to presenting the program. A maximum of 2 hours may be earned in each renewal period.
(i)	Attendance at a pharmacy-related program that is approved by the board pursuant to R 338.3043. If audited, a licensee shall submit a copy of a letter or certificate of completion showing all of the following: Licensee's name. Number of hours earned. Sponsor name or the name of the organization that approved the program or course for continuing education credit. The date on which the program was held, or the activity was completed.	The number of hours earned ~~will be~~ **is** the number of hours approved by the sponsor or the approving organization. If the activity was not approved for a set number of hours, then 1 credit hour for every 50 minutes of participation ~~may be~~ **is** earned. **There is no** ~~No~~ limitation on the number of hours earned.

(j)	Attendance at a full board of pharmacy meeting, disciplinary subcommittee meeting, or rules committee work group meeting. **To receive credit for attending a meeting in person, a licensee shall obtain a form provided by the department from a department employee present at the meeting and have the employee complete, sign, and date the form.** **To receive credit for attending a meeting virtually, a licensee shall submit an electronic form provided by the department.** **If audited, a licensee shall provide a copy of the completed paper form or electronic confirmation.**	One hour ~~may be~~ **is** earned for attending a full meeting. This category of continuing education qualifies as 1 hour in pharmacy law. A maximum of 5 hours may be earned in each renewal period.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

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(By authority conferred on the director of the department of licensing and regulatory affairs by sections 16141, 16145, 16148, 16174, 16175, 16178, 16182, 16186, **16201,** 16204, 16205, 16215, 16287, 17707, ~~17721,~~ 17722, **17724, 17724a,** 17731, 17737, 17739, 17742a, 17742b, 17744f, **17744g,** 17746, 17748, 17748a, 17748b, 17748e, 17751, 17753, 17754a, 17757, 17760, 17767, and 17775 of the public health code, 1978 PA 368, MCL 333.16141, 333.16145, 333.16148, 333.16174, 333.16175, 333.16178, 333.16182, 333.16186, **333.16201,** 333.16204, 333.16205, 333.16215, 333.16287, 333.17707, ~~333.17721,~~ 333.17722, **333.17724, 333.17724a,** 333.17731, 333.17737, 333.17739, 333.17742a, 333.17742b, 333.17744f, **333.17744g,** 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17748e, 333.17751, 333.17753, 333.17754a, 333.17757, 333.17760, 333.17767, and 333.17775 and Executive Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.501, R 338.511, R 338.513, R 338.521, R 338.523, R 338.525, R 338.531, R 338.531a, R 338.533, R 338.534, R 338.534a, R 338.551, R 338.555, R 338.563, and R 338.583 of the Michigan Administrative Code are amended, and R 338.507, R 338.532a, R 338.581, R 338.581a, R 338.581b, R 338.581c, R 338.581d, and R 338.592 are added, as follows:

PART 1. GENERAL PROVISIONS

R 338.501 Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) "Contraceptive" means a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive eligible for dispensing under section 17744g of the code, MCL 333.17744g.

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

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

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

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

~~(k)~~**(l)** "Error prevention technology" means machinery and equipment used in a pharmacy setting to reduce dispensing medication errors including, but not limited to, barcode verification and radio frequency identification.

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

(n) "FDCA" means the federal food, drug, and cosmetic act, 21 USC 301 to 399d.

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

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

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

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

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

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

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

~~(t)~~**(v)** "PIC" means pharmacist in charge.

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

(i) Pharmacy administration and management.

(ii) Drug distribution, use, and control.

(iii) Legal requirements.

(iv) Providing health information services and advising patients.

(v) Pharmacist's ethical and professional responsibilities.

(vi) Drug and product information.

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

~~(v)~~**(x)** "USP" means the United States Pharmacopeia.

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

(i) Owns either of the following:

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

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

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

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

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

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

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

(2) Unless otherwise defined in these rules, the terms defined in the code have the same meaning as used in these rules.

R 338.507 Telehealth.

Rule 7. (1) A health professional shall obtain consent from the patient for treatment before providing a telehealth service under section 16284 of the code, MCL 333.16284.

(2) A health professional shall keep proof of consent for telehealth treatment in the patient's up-to-date medical record and satisfy section 16213 of the code, MCL 333.16213.

(3) A pharmacist providing a telehealth service may prescribe a drug if the pharmacist is a prescriber acting within the scope of the pharmacist's practice and complies with section 16285 of the code, MCL 333.16285, and if the pharmacist does both of the following:

(a) Refers the patient to a provider that is geographically accessible to the patient, if medically necessary.

(b) Makes the pharmacist available to provide follow-up care services to the patient, or to refer the patient to another provider, for follow-up care.

(4) A health professional providing any telehealth service shall do both of the following:

(a) Act within the scope of the health professional's practice.

(b) Exercise the same standard of care applicable to a traditional, in-person healthcare service.

PART 2. PHARMACIST LICENSES

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Teleconference or webinar.

(ii) Online presentation.

(iii) Live presentation.

(iv) Printed or electronic media.

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

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

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

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

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

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

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

(a) That the applicant is actively enrolled in, or is within 180 days of completing, an approved educational program.

(b) That the applicant has received a FPGEC certification from the NABP Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, Illinois, 60056, https://nabp.pharmacy/programs/fpgec/.

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

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

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

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

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

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

(6) An applicant for an educational limited license shall meet the requirements of R 338.511 and R 338.7004.

R 338.521 Pharmacist licensure by examination.

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

(2) In addition to meeting the requirements of section 16174 of the code, MCL 333.16174; R 338.7001 to R 338.7005; and any other rules promulgated under the code, an applicant for licensure shall satisfy all of the following requirements:

(a) Obtain ~~one~~ **1** of the following:

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

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

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

(b) Pass the NAPLEX.

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

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

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

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

(3) An applicant ~~that~~ **who** is or has ever been licensed, registered, or certified in a health profession or specialty by another state, the United States military, the federal government, or another country, shall do both of the following:

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

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

R 338.523 Pharmacist license by endorsement; requirements.

Rule 23. (1) An applicant ~~that~~ **who** has never held a pharmacist license in this state and is licensed in another state or Canada, may apply for licensure as a pharmacist by endorsement by submitting to the department a completed application on a form provided by the department with the requisite fee. An applicant ~~that~~ **who** meets the requirements of this rule, R 338.7001 to R 338.7005, and any other rules promulgated under the code is presumed to meet the requirements of section 16186 of the code, MCL 333.16186.

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

(a) Establish 1 of the following:

(i) The applicant holds a license in good standing as a pharmacist in another state and submits the NABP licensure transfer report to the department.

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

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

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

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

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

(c) An applicant ~~that~~ **who** is or has ever been licensed, registered, or certified in a health profession or specialty by another state, the United States military, the federal government, or another country, shall do both of the following:

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

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

(d) The applicant meets section 16174 of the code, MCL 333.16174, and submits ~~his or her~~ **the applicant's** fingerprints to the department of state police to have a criminal background check conducted by the state police and the Federal Bureau of Investigation.

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

(f) The applicant completes ~~a 1-time~~ training in opioids and other controlled substances awareness as required in R 338.3135.

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

R 338.525 Relicensure of a pharmacist license; requirements.

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

For a pharmacist who**se** ~~has let his or her~~ license **has** lapse**d** in this state and is not currently licensed in **good standing in** another state or a province of Canada:	License lapsed 0-3 years.	License lapsed more than 3 years, but less than 8 years.	License lapsed 8 or more years.
(a) Submit to the department a completed application on a form provided by the department with the requisite fee.	X	X	X
(b) Establish that the applicant is of good moral character as that term is defined in, and determined under, 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) Submit proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately before the application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years after the date of the application to complete the deficient hours. The application must be held and the license may not be issued until the continuing education requirements are met.	X	X	X

(e) Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.		X	X
(f) Submit proof of completing a 1-time training in identifying victims of human trafficking as required in R 338.511, ~~a 1-time~~ training in opioids and other controlled substances awareness as required in R 338.3135, and implicit bias training as required in R 338.7004.	X	X	X
(g) Complete 200 hours of practical experience under the personal charge of a pharmacist currently licensed in this state who is located in or outside of this state, within 6 months after being granted a limited license.		X	
(h) Complete 400 hours of practical experience under the personal charge of a pharmacist currently licensed in this state who is located in or outside of this state, within 6 months after being granted a limited license.			X
(i) Retake and pass the NAPLEX within 2 years before applying for relicensure, as provided in R 338.519.			X
(j) An applicant ~~that~~ **who** is or has ever been licensed, registered, or certified in a health profession or specialty by another state, the United States military, the federal government, or another country, shall do both of the following: (i) Disclose each license, registration, or certification on the application form. (ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, including verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.	X	X	X

(2) As used in subrule (1)(g) and (h) of this rule, an applicant may be granted a non-renewable limited license to complete the practical experience.

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

(4) For a pharmacist who**se** ~~has let his or her~~ pharmacist license **has** lapse**d** in this state, but who holds a current and valid pharmacist license in good standing in another state or a Canadian province:	License lapsed 0-3 years.	License lapsed more than 3 years, but less than 8 years.	License lapsed 8 or more years.
(a) Submit to the department a completed application on a form provided by the department with the requisite fee.	X	X	X
(b) Establish that the applicant is of good moral character as that term is defined in, and determined under, 1974 PA 381, MCL 338.41 to MCL 338.47.	X	X	X
(c) Submit fingerprints as required under section 16174(3) of the code, MCL 333.16174.		X	X
(d) Submit proof of completing 30 hours of continuing education that satisfy R 338.3041 to R 338.3045 in the 2 years immediately before the application for relicensure. However, if the continuing education hours submitted with the application are deficient, the applicant has 2 years after the date of the application to complete the deficient hours. The application must be held and the license may not be issued until the continuing education requirements are met.	X	X	X
(e) Submit proof of completing a 1-time training in identifying victims of human trafficking as required in R 338.511, ~~a 1-time~~ training in opioids and other controlled substances awareness as required in R 338.3135, and implicit bias training as required in R 338.7004.	X	X	X
(f) Provide an attestation to the department that the applicant has sufficient knowledge of the code and the board's rules to competently practice pharmacy in this state.		X	X

(g) An applicant ~~that~~ **who** is or has ever been licensed, registered, or certified in a health profession or specialty by another state, the United States military, the federal government, or another country, shall do both of the following: (i) Disclose each license, registration, or certification on the application form. (ii) Satisfy the requirements of section 16174(2) of the code, MCL 333.16174, including verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.	X	X	X

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

PART 3. PHARMACY LICENSES

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

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

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

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

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

(c) A FEIN certificate.

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

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

(f) A completed self-inspection form.

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

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

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

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

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

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

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

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

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

(ii) Submit verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

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

R 338.531a Remote pharmacy waiver from mileage requirement.

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

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

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

(b) A list and explanation of the services or availability of services that will be offered at the remote pharmacy or otherwise not readily available to patients that are different from the services offered at a pharmacy located within 10 miles of the proposed remote pharmacy.

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

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

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

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

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

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

R 338.532a Outsourcing facilities; board approval; inspection entities.

Rule 32a. (1) The board shall approve, under section 17748a of the code, MCL 333.17748a, inspection entities for outsourcing facilities that compound pharmaceuticals under current and as amended good manufacturing practice for finished pharmaceuticals set forth in 21 CFR part 211.

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

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

(a) Requirements for compliance.

(b) Requirements for inspectors.

(c) Training provided to inspectors.

(d) Copy of the most current inspection form.

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

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

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

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

Rule 33. (1) The board approves and adopts by reference the compounding standards of USP, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852-1790. This includes USP Chapters 795 (revised 2023)**,** ~~and~~ 797 ~~(~~revised ~~2023~~**2024**), **800 (revised 2020), and 825 (revised 2024),** with the exception of flavoring.

(2) The standards adopted by reference in subrule (1) of this rule are available ~~at a cost of $250.00 at http://www.usp.org/compounding, or can be viewed at the Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.~~ **from the USP Compounding Compendium at https://www.usp.org/products/usp-compounding-compendium through a 1-year online subscription at a cost of $250.00 as of the time of adoption of this rule. The standards adopted by reference in subrule (1) are available for inspection at the Bureau of Professional Licensing,**

Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.

(3) A pharmacy that provides compounding services **under section 503A of the FDCA, 21 USC 353a,** shall comply with the standards adopted in subrule (1) of this rule.

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

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

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

(b) Within 6 months after initial licensure under this subrule, a pharmacy shall obtain, and provide to the department, a subsequent inspection to assess adherence to the current and as amended good manufacturing ~~practices~~**practice** for finished pharmaceuticals set forth in 21 CFR ~~211.1 to 211.208.~~**part 211.**

(6) A~~n~~ **pharmacy registered as an** outsourcing facility **or a pharmacy located in this state that compounds drugs under section 503B of the FDCA, 21 USC 353b,** shall do all of the following:

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

(b) Compound drugs under current good manufacturing ~~practices~~ **practice** for finished pharmaceuticals set forth in 21 CFR ~~211.1 to 211.208.~~**part 211.**

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

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

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

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

(i) Required drug and ingredient information.

(ii) Facility identification.

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

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

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

R 338.534 Out-of-state pharmacy licensure inspection; in-state pharmacy licensure renewal inspection**; outsourcing facility licensure renewal inspection**.

Rule 34. (1) A pharmacy located outside of this state that applies for licensure in this state as a pharmacy that will not ship compounded sterile pharmaceutical products into

this state shall submit to the department a copy of its most recent resident state board of pharmacy inspection or an NABP-VPP inspection that was performed within the last 2 years before the date of application.

(2) Unless accredited by a national accrediting organization, recognized by the board, an applicant for renewal of an in-state pharmacy license, or an applicant for an initial or renewal of an out-of-state pharmacy license, that will provide sterile compounded pharmaceuticals in this state **and is not registered as an outsourcing facility** shall have an inspection and submit the inspection report to the department, completed no more than 18 months before the date of application, that demonstrates compliance with all applicable standards that are adopted by reference in R 338.533. The inspection must be conducted by 1 of the following:

(a) The department.

(b) The NABP-VPP.

(c) An accrediting organization according to R 338.532.

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

(3) A pharmacy that compounds drugs under section 503B of the FDCA, 21 USC 353b, and is applying for license renewal shall have an inspection and submit the inspection report to the department, completed no more than 18 months before the date of the application, that demonstrates compliance with the current and as amended good manufacturing practice for finished pharmaceuticals set forth in CFR part 211. The inspection must be conducted by 1 of the following:

(a) The FDA.

(b) An inspection organization according to R 338.532a.

R 338.534a In-state initial pharmacy license inspections.

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

(2) An applicant for an in-state pharmacy license that intends to compound sterile pharmaceutical products **under section 503A of the FDCA, 21 USC 353a,** shall complete both of the following:

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

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

(3) Approval to engage in sterile compounding **under section 503A of the FDCA, 21 USC 353a,** will end 6 months after initial licensure if a subsequent inspection to assess USP compliance or accreditation is not successful.

PART 4. MANUFACTURER LICENSE

R 338.551 Manufacturer license; application.

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

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

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

(b) A FEIN certificate.

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

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

(e) A completed compliance checklist for manufacturers.

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

(g) Unless exempt under section 17748(2) of the code, MCL 333.17748, the name and license number of the pharmacist designated as the PIC or the name of the facility manager. If a PIC or facility manager is unable to ~~fulfil~~ **fulfill** ~~his or her~~**the PIC or facility manager's** duties for 120 consecutive days, the pharmacy shall appoint a new PIC or facility manager and notify the department as required in section 17748(4) of the code, MCL 333.17748. For an individual who is designated as a facility manager, the applicant shall provide proof, in the form of an affidavit, that the facility manager has achieved the following:

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

(A) A high school diploma.

(B) A GED.

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

(iii) Experience equal to either of the following:

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

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

(iv) Employment with the applicant.

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

(i) An inspection from the FDA, or manufacturer's resident state board of pharmacy, that is dated not more than 2 years before application or current NABP drug distributor accreditation.

(j) An applicant that is or has ever been licensed, registered, or certified as a manufacturer by another state, the United States military, the federal government, or another country, shall do both of the following:

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

(ii) Submit verification from the issuing entity showing that disciplinary proceedings are not pending against the applicant and sanctions are not in force at the time of application.

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

(4) A manufacturer ~~who~~ **that** changes its facility manager shall submit all of the information required in subrule (2)(g) of this rule to the department within 30 days after the change.

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

Rule 55. (1) The board approves and adopts by reference the current ~~and as amended~~ good manufacturing practice for finished pharmaceuticals regulations set forth in 21 CFR ~~211.1 to 211.208~~**part 211** ~~(2022)~~.

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

(3) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211, or at ~~10~~**25** cents per page from the Board of Pharmacy, Bureau of Professional Licensing, Michigan Department of Licensing and Regulatory Affairs, Ottawa Building, 611 West Ottawa, P.O. Box 30670, Lansing, Michigan 48909.

PART 5. WHOLESALE DISTRIBUTOR AND WHOLESALE DISTRIBUTOR-BROKER LICENSE

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

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

(2) An applicant shall comply with all of the following:

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

(b) Disclose on the application form each license, registration, or certification in a health profession or specialty issued by another state, the United States military, the federal government, or another country.

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

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

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

(f) Provide a completed compliance checklist.

(g) Provide a FEIN certificate.

(h) Unless exempt under section 17748(2) of the code, MCL 333.17748, provide the name and the license number of the pharmacist designated as the PIC or the name of the facility manager. If a PIC or facility manager is unable to ~~fulfil~~ **fulfill** ~~his or her~~**the PIC or facility manager's** duties for 120 consecutive days, the pharmacy shall appoint a new PIC or facility manager and notify the department as required in section 17748(4) of the code, MCL 333.17748. For individuals designated as a facility manager, the applicant shall provide proof, in the form of an affidavit, that the facility manager has achieved the following:

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

(A) A high school diploma.

(B) A GED.

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

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

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

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

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

(C) Knowledge and understanding of quality control systems.

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

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

(iii) Experience equal to either of the following:

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

(B) Previous or current employment as a designated representative of a wholesale distributor certified by the NABP drug distributor accreditation or of a wholesale distributor-broker.

(iv) Current employment with the applicant.

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

(j) If a wholesale distributor-broker, submit an affidavit, at the time of the application for initial licensure, that the applicant facilitates deliveries or trades for not less than 50

qualified pharmacies and that each pharmacy holds a license in good standing as a pharmacy from the state in which it is located at the time of application.

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

PART 6. PRACTICE OF PHARMACY

R 338.581 Ordering and administration of qualified immunizing agent; training program.

Rule 81. Before ordering and administering a qualified immunizing agent under section 17724 of the code, MCL 333.17724, a pharmacist shall successfully complete a training course on the administration of vaccines that is provided by an entity accredited by the ACPE.

R 338.581a Ordering and administration of qualified laboratory test; dispensing drug without prescription based on test result; training program.

Rule 81a. (1) Before ordering and administering a qualified laboratory test and dispensing, without a prescription, a drug based on the test result, under section 17724a of the code, MCL 333.17724a, a pharmacist shall complete a training program requiring the pharmacist to demonstrate sufficient knowledge of how to administer and interpret each laboratory test that the pharmacist may order or administer under section 17724a of the code, MCL 333.17724a, and demonstrate sufficient knowledge of each illness, condition, or disease for which the pharmacist provides treatment based on the results of the laboratory test.

(2) Any of the following is acceptable to meet the requirements of subrule (1) of this rule:

(a) Employer-based training.

(b) Training completed as part of a professional degree from a school of pharmacy accredited by the ACPE.

(c) A certificate program.

R 338.581b Pharmacist prescribing a contraceptive; board-approved training program required.

Rule 81b. Before issuing a prescription for a contraceptive under section 17744g of the code, MCL 333.17744g, a pharmacist shall successfully complete a training course on prescribing and dispensing contraceptives that is provided by an entity accredited by the ACPE.

R 338.581c Prescribing and dispensing a contraceptive; standard procedure.

Rule 81c. A pharmacist who issues a prescription for a contraceptive under section 17744g of the code, MCL 333.17744g, shall comply with the following standard procedure:

(a) Before issuing the prescription, the pharmacist shall comply with both of the following:

(i) Require the patient to complete the self-screening risk assessment tool described in R 338.581d and R 338.592. A pharmacist is prohibited from issuing a contraceptive prescription to an individual who has not completed the self-screening risk assessment tool.

(ii) Review the patient's completed self-screening risk assessment tool before issuing a prescription for contraceptive and use the pharmacist's clinical judgment to determine whether prescribing a contraceptive is appropriate to the patient's health status.

(b) Upon issuing a prescription for a contraceptive, the pharmacist shall comply with all of the following:

(i) Refer the patient to the patient's primary care physician, or if the patient does not have a primary care physician, to another licensed heath professional that the pharmacist considers appropriate.

(ii) If the patient has not had a physical examination in the previous 12 months, the pharmacist shall refer the patient to the patient's primary care provider for a physical examination.

(iii) If the pharmacist does not issue a prescription, the pharmacist shall refer the patient to a primary care physician or another licensed heath professional that the pharmacist considers appropriate.

(iv) Provide the patient with a written record of the prescribed contraceptive for which the patient is issued a prescription and advise the patient to consult with a physician or other licensed health professional.

(v) Dispense the prescribed contraceptive as soon as practicable. The prescription must be transferred to a pharmacy of the patient's choice for dispensing, if requested.

R 338.581d Self-screening risk assessment tool.

Rule 81d. (1) A pharmacist is prohibited from issuing a prescription for a contraceptive to an individual who has not completed the self-screening assessment tool found in Appendix A in R 338.592, or a substantially similar self-screening assessment tool under subrule (2) of this rule.

(2) A self-screening risk assessment tool is substantially similar to the tool found in Appendix A in R 338.592 if it requires, at a minimum, the same information from the patient as Appendix A in R 338.592. The questions in Appendix A in R 338.592 may be reordered or reformatted. The patient may complete the self-screening risk assessment tool electronically.

R 338.583 Prescription drug receipts.

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

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

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

(c) The strength of the drug, if significant, unless the prescriber ~~or~~ **r** indicates "do not label."

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription.

(g) The date the prescription was dispensed.

(h) The name of the prescriber.

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

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

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

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

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

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

R 338.592 Appendix A; self-screening risk assessment tool questions.

Rule 92. Appendix A – Self-screening risk assessment tool questions.

1. Do you smoke cigarettes or e-cigarettes?

2. Do you think you might be pregnant now?

2a. Start date of last period: _____.

3. Are you experiencing any of the following:

- □ **Nausea/vomiting.**
- □ **Tender/swollen breasts.**
- □ **Increased urination.**
- □ **Fatigue.**
- □ **None apply.**

4. Which of the following are true for you?

- □ **I have been using a reliable contraceptive method consistently and correctly.**
- □ **I have not had sexual intercourse since my last period or delivery.**
- □ **I have given birth in the last 6 weeks.**
- □ **I have lost a pregnancy in the last 7 days.**

□ **I have been fully or nearly-fully breastfeeding for 6 months or less AND not had a menstrual period since delivery.**

□ **None of these apply to me.**

5. Please select all that apply to you:

□ **Used birth control (pills/patch/ring/shot/injection) in the past.**

□ **Currently using birth control (pills/patch/ring/shot/injection).**

Drug name:

□ **Have had a bad reaction to hormonal birth control in the past.**

Drug name:

Reaction:

□ **None of these apply to me.**

6. Please select all that you have been diagnosed with in the past or that apply to you currently:

□ **Breast cancer.**

□ **Ischemic heart disease.**

□ **Heart attack or stroke.**

□ **Severe/decompensated liver cirrhosis.**

□ **Malignant liver tumor.**

□ **Hepatocellular adenoma.**

□ **Chronic kidney disease.**

□ **On dialysis.**

□ **Unexplained vaginal bleeding.**

□ **Complicated organ transplant.**

□ **Blood clot in lung or leg.**

□ **High cholesterol.**

□ **Hepatitis.**

□ **Blood disorder.**

□ **Gall bladder disease.**

□ **Inflammatory bowel disease (Crohn's, UC).**

□ **Jaundice (yellowing of skin/eyes).**

□ **Upcoming major surgery in next 4 weeks.**

□ **Lupus.**

□ **High blood pressure.**

□ **Other heart or valve disease.**

□ **Bariatric or stomach reduction surgery.**

□ **Sickle cell disease.**

□ **None apply.**

7. Have you ever been told by a medical professional not to take hormones?

8. Have you ever been told by a medical professional you are at risk of developing a blood clot?

9. Do you take medication for seizures, tuberculosis (TB), fungal infections, or HIV?

9a. If yes, list them here: _____

10. Do you have any conditions or upcoming procedures that will cause you to be immobile for a prolonged period of time? (e.g., recent/upcoming surgery, multiple sclerosis, etc.)

11. Do you get migraine headaches or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or involves numbness?
11a. If yes, do these headaches ever start with flashes of light, blind spots, or tingling in your hand or face that come and go away completely before the headache starts?
12. Do you have diabetes or other vascular disease other than Gestational Diabetes?
12a. Due to diabetes I have:

- □ **Nerve pain or tingling.**
- □ **Pain, numbness, or weakness in hands or feet.**
- □ **Kidney damage.**
- □ **Vision or eye damage.**
- □ **None apply.**

13. Have you ever been diagnosed with rheumatoid arthritis?
14. Do you have any other medical problems or take regular medications?
14a. If yes, list them here:____
15. Do you have any drug allergies?
15a. If yes, list them here: