MICHIGAN BOARD OF PHARMACY
RULES COMMITTEE WORK GROUP
MEETING

MINUTES
November 4, 2024

The Michigan Board of Pharmacy Rules Committee Work Group met on November 4, 2024. The meeting was held via Zoom.

CALL TO ORDER

Jennifer Shaltry, JD, Departmental Specialist, called the meeting to order at 1:00 p.m.

ATTENDANCE

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

Members Absent: Pierre Boutros, R.Ph.

Staff Present: Jennifer Shaltry, JD, Departmental Specialist,
Boards and Committees Section
Kim Smith, Board Support Technician,
Boards and Committees Section
LeAnn Payne, Board Support Technician,
Boards and Committees Section
Amy Freeman, Department Analyst, Licensing Section
Christina Koehler, Manager, Licensing Section
Jodi Cornell, Director, Data Services Division

Public Present: Eric Roath. Michigan Pharmacists Assoc.
Mary Hein, R.Ph
Justine Nelson
Maria Young
Rod Larson
Hannah Sowan
Susan Davis

Mitchell Aytay
Christopher Jones
Jonathan McLaren
Deeb D. Eid
Amy Thompson
Maureen

RULES DISCUSSION

PHARMACY – PHARMACIST CONTINUING EDUCATION

R 338.3044(4) Acceptable continuing education for licensees.
Subdivision (a)

Shaltry presented language to add a 5-hour limitation on continuing education.

Discussion was held.

The committee agreed to the language.

Shaltry discussed receiving continuing education credit for attending a Board of Pharmacy Meeting over Zoom and what was the best way to validate attendance for participants. She suggested having those seeking credit to drop their name in the chat or have staff add verbiage on the agenda regarding obtaining credit.

Discussion was held.

Shaltry discussed having a form for staff to sign for those who attend in person seeking continuing education credit.

The committee agreed to do whatever was easiest for staff. Shaltry will work on a plan and discuss at next board meeting.

PHARMACY - GENERAL RULES

R 338.503 Prescription drugs and devices; return or exchange for resale prohibited.
Shaltry explained there was a question from the department regarding Rule 1 and if “for resale” applies to both returns and exchanges.

Discussion was held.

Committee agreed to keep the language as it is currently written.

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

Rule 81a. (1) Shaltry explained that the training program that must be completed by a pharmacist needs to be better defined.

Sleiman asked if language from the statute could be used.

Shaltry said no because that language did not explain what programs would be sufficient.

Sesi said she wanted to keep it vague and possibly use a module as a training program.

Shaltry suggested employer-based training or training that was completed as part of pharmacy school.

Sesi suggested the following language:

A pharmacist shall complete a training program which demonstrates they can order and administer within the standard of care. The training program shall demonstrate a pharmacist has shown competence in accordance with standards of practice.

Committee agreed with the new language.

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

Shaltry explained to the committee that the enforcement date for long-term care is January 1, 2025, and subrules (1) and (2) will no longer be needed.

Committee agreed with this change.

PUBLIC COMMENT

Roath explained that existing certification programs that are ACPE accredited should be a part of the sufficient training programs under **R 338.581a**

ADJOURNMENT

Shaltry adjourned the meeting at 1:26pm

Prepared by:
Kim Smith, Board Support Technician November 8, 2024
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, etc of the Michigan Administrative Code is 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.

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

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

(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 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 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. No limitation on the number of hours earned**, except that a maximum of 5 hours may 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 earned for each academic quarter credit earned and 18 hours will be earned for each academic semester credit earned. No limitation on the number of

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	the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.	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 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 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. The date on which the program was held,	Thirty hours will be earned. A maximum of 30 hours may be earned in each renewal period.

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	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 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 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 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 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 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 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. No limitation on the number of hours earned.
(j)	**In-person** ~~A~~**a**ttendance at a full board of	One hour may be earned for

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	pharmacy meeting~~,~~ **or** disciplinary subcommittee meeting~~, or rules committee work group meeting~~. **To receive credit, 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.** **If audited, a licensee shall provide a copy of the form completed, signed, and dated by the department employee who was present at the meeting.**	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.

The department proposes the above revisions to R 338.3044 (j) making only in-person meeting attendance eligible for continuing education credit.

Alternatively, the department proposes that the continuing education hours for meeting attendance be reduced:

(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 a statement of the licensee's full name in the chat when prompted by department staff. Alternatively, a licensee who is unable to use the chat function may state their name full name when prompted by department staff. A licensee attending a meeting virtually who does not remain logged in for the entire meeting is not eligible to receive credit for attending the meeting.** **If audited, a licensee shall provide a copy of the form completed, signed, and dated by the department employee who was present at the meeting or a copy of the meeting minutes evidencing the licensee's**	One-**half** hour may be earned for attending a full meeting. This category of continuing education qualifies as 1/**2** hour in pharmacy law. A maximum of 5 hours may be earned in each renewal period.

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	virtual attendance at the meeting. Meeting minutes are available at: https://www.michigan.gov/lara/bureau-list/bpl/health/hp-lic-health-prof/pharmacy/board/pharmacy-board-meeting-agendas-and-minutes.	

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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, 16204, 16205, 16215, 16287, 17707, 17721, 17722, 17731, 17737, 17739, 17742a, 17742b, 17744f, 17746, 17748, 17748a, 17748b, 17748e, 17751, 17753, 17754a, 17757, 17760, 17767, and 17775 of the public health code, 1978 PA 368, MCL 333.16141, 333.16145, 333.16148, 333.16174, 333.16175, 333.16178, 333.16182, 333.16186, 333.16204, 333.16205, 333.16215, 333.16287, 333.17707, 333.17721, 333.17722, 333.17731, 333.17737, 333.17739, 333.17742a, 333.17742b, 333.17744f, 333.17746, 333.17748, 333.17748a, 333.17748b, 333.17748e, 333.17751, 333.17753, 333.17754a, 333.17757, 333.17760, 333.17767, and 333.17775 and Executive Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030)

R 338.486, etc of the Michigan Administrative Code is amended as follows:

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PART 1. GENERAL PROVISIONS

R 338.507 Telehealth.

Rule 92. (1) A licensee shall obtain consent from the patient for treatment before providing a telehealth service under section 16284 of the code, MCL 333.16284.

(2) A licensee 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 licensee providing any telehealth service shall do both of the following:

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

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

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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 of the following:

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

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

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

(b) Pass the NAPLEX.

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

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

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

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

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

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

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

R 338.523 Pharmacist license by endorsement; requirements.

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

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

(a) Establish 1 of the following:

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

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

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

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

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

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

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

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

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

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(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 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 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

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

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

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(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 is or has ever been	X	X	X

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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.			

(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.

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(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.

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

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

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

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

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

(a) Requirements for accreditation or compliance.

(b) Requirements for inspectors.

(c) Training provided to inspectors.

(d) Copy of the most current inspection form.

(e) The length of accreditation.

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

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

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

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

Rule 33. (1) The board approves and adopts by reference the compounding standards of USP, published by the United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852-1790. This includes **~~the 2023 revisions of~~** 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.

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

(4) An outsourcing facility located outside of this state that dispenses, provides, distributes, or otherwise furnishes compounded pharmaceuticals in this state shall be

inspected and registered as an outsourcing facility by the FDA before applying for a pharmacy license in this state.

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

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

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

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

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

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

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

(i) Participating in seminars.

(ii) Studying appropriate literature.

(iii) Consulting with colleagues.

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

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

(i) Required drug and ingredient information.

(ii) Facility identification.

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

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

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

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.

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

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

(e) A completed compliance checklist for manufacturers.

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

(g) Unless exempt under section 17748(2) of the code, MCL 333.17748, the name and license number of the pharmacist designated as the PIC or the name of the facility manager. If a PIC or facility manager is unable to fulfil ~~his or her~~**their** 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.

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

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

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

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

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

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

(3) The standards adopted by reference in subrule (1) of this rule are available at no cost at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211, or at ~~10~~**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.

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

(f) Provide a completed compliance checklist.

(g) Provide a FEIN certificate.

(h) Unless exempt under section 17748(2) of the code, MCL 333.17748, provide the name and the license number of the pharmacist designated as the PIC or the name of the facility manager. If a PIC or facility manager is unable to fulfil ~~his or her~~**their** 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.

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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, 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 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):

(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.

Further revisions to R 338.581a will be discussed with the Board of Pharmacy.

R 338.583 Prescription drug receipts.

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

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

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

(c) The strength of the drug, if significant, unless the prescribe~~d~~**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.

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

Rule 84a. ~~(1) Until the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement a prescription may be electronically transmitted, and a pharmacist may dispense the electronically transmitted prescription, if all of the following conditions are satisfied:~~

~~(a) The prescription is transmitted to the pharmacy of the patient's choice and occurs only at the option of the patient.~~

~~(b) The electronically transmitted prescription includes all of the following information:~~

~~(i) The name and address of the prescriber.~~

~~(ii) An electronic signature or other board-approved means of ensuring prescription validity.~~

~~(iii) The prescriber's telephone number for verbal confirmation of the order.~~

~~(iv) The time and date of the electronic transmission.~~

~~(v) The name of the pharmacy intended to receive the electronic transmission.~~

~~(vi) Unless as otherwise authorized under section 17754(1)(b) of the code, MCL 333.17754, the full name of the patient for whom the prescription is issued.~~

~~(vii) All other information that must be contained in a prescription under R 338.584.~~

~~(c) The pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the transmitted prescription.~~

~~(d) All requirements in section 17754 of the code, MCL 333.17754, are met.~~

~~(2) An electronically transmitted prescription that meets the requirements of subrule (1) of this rule is the original prescription.~~

(~~3~~**1**) Effective the enforcement date established by the federal Centers for Medicare and Medicaid Services for the Medicare electronic transmission requirement prescribers shall, unless an exception under section 17754a of the code, MCL 333.17754a, applies, electronically transmit a prescription consistent with both of the following requirements:

(a) All the requirements in section 17754a of the code, MCL 333.17754a, are met.

(b) All the requirements in R 338.584 are met.

~~(4)~~**(2)** A prescriber applying for a waiver from section 17754a of the code, MCL 333.17754a, shall submit a completed application to the department, on a form provided by the department, and shall satisfy either of the following requirements:

(a) The prescriber provides evidence satisfactory to the department that the prescriber has received a waiver of the Medicare requirement for the electronic transmission of controlled substances prescriptions from the federal Centers for Medicare and Medicaid Services.

(b) The prescriber is unable to meet the requirements of section 17754a(1) or (2) of the code, MCL 333.17754a, and also meets 1 of the following:

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

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

(iii) The prescriber demonstrates by attesting to exceptional circumstances, including, but not limited to, the following:

(A) Intention to cease practice within the next twelve months.

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

(iv) The prescriber issues prescriptions from a non-profit charitable medical clinic.

(~~5~~**3**) A waiver is valid for 2 years and is applicable to the specific circumstances included in the application. A waiver may be renewed by application to the department.

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