

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

June 26, 2023

NOTICE OF FILING

ADMINISTRATIVE RULES

To: Secretary of the Senate

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Clerk of the House of Representatives Joint Committee on Administrative Rules Michigan Office of Administrative Hearings and Rules (Administrative Rule #21-051-LR) Legislative Service Bureau (Secretary of State Filing #23-06-10) Department of Licensing and Regulatory Affairs

In accordance with the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6, this is to advise you that the Michigan Office of Administrative Hearings and Rules filed Administrative Rule #2021-051-LR (Secretary of State Filing #23-06-10) on this date at 12:41 P.M. for the Department of Licensing and Regulatory Affairs entitled, "Pharmacy- Pharmacist Continuing Education".

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

Sincerely,

Jocelyn Benson Secretary of State

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Lashana Threlkeld, Departmental Supervisor Office of the Great Seal

Enclosure



GRETCHEN WHITMER GOVERNOR

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

ORLENE HAWKS DIRECTOR

June 26, 2023

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

Dear Secretary Benson:

Re: Administrative Rules – Michigan Office of Administrative Hearings and Rules Administrative Rules #: 2021-51 LR

The Michigan Office of Administrative Hearings and Rules received administrative rules, dated February 2, 2023 for the Department of Licensing & Regulatory Affairs **"Pharmacy - Pharmacist Continuing Education".** We are transmitting these rules to you pursuant to the requirements of Section 46 of Act No. 306 of the Public Acts of 1969, being MCL 24.246, and paragraph 16 of Executive Order 1995-6.

Sincerely,

Michigan Office of Administrative Hearings and Rules



GRETCHEN WHITMER GOVERNOR

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DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

ORLENE HAWKS DIRECTOR

LEGAL CERTIFICATION OF RULES

I certify that I have examined the attached administrative rules, dated February 2, 2023, in which the Department of Licensing and Regulatory Affairs proposes to modify a portion of the Michigan Administrative Code entitled "**Pharmacy – Pharmacist Continuing Education**" by:

- Amending R 338.3041, R 338.3043, and R 338.3044.
- Adding R 338.3042.

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

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

Dated: May 2, 2023

Michigan Office of Administrative Hearings and Rules

By:

Emily Leik

Emily Leik, Attorney



Since 1941

Kevin H. Studebaker, Director

CERTIFICATE OF APPROVAL

On behalf of the Legislative Service Bureau, and as required by section 45 of the Administrative Procedures Act of 1969, 1969 PA 306, MCL 24.245, I have examined the proposed rules of the Department of Licensing and Regulatory Affairs dated February 2, 2023, amending R 338.3041, R 338.3043, and R 338.3044 and adding R 338.3042 of the Department's rules entitled "Pharmacy – Pharmacist Continuing Education." I approve the rules as to form, classification, and arrangement.

Dated: May 2, 2023

LEGISLATIVE SERVICE BUREAU

By

Rachel M. Hughart, Legal Counsel



GRETCHEN WHITMER GOVERNOR STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

CERTIFICATE OF ADOPTION

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 338.3043, and R 338.3044 of the Michigan Administrative Code are amended, and R 338.3042 is added.

Date: 04/21/2023

Adopted by:

Marlon I. Brown Chief Administrative Officer Department of Licensing and Regulatory Affairs

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PHARMACIST CONTINUING EDUCATION

Filed with the secretary of state on June 26, 2023

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

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 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 338.3043, and R 338.3044 of the Michigan Administrative Code are amended, and R 338.3042 is added, as follows:

R 338.3041 Definitions.

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

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

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

(c) "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 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 before the expiration date of the license.

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

R 338.3043 Continuing education courses and programs; standards for approval.

Rule 3. The board shall approve continuing education courses or programs pursuant to the following standards in this rule:

(a) A continuing education course or program sponsor shall submit a completed application on forms provided by the department and provide a "Patient Protection" form for any course or program that involves treatment of live patients.

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(b) A completed application form shall be submitted to the department at least 70 days before the date the continuing education course or program is conducted for the proposed continuing education to be considered for approval by the board.

(c) A continuing education course or program must meet the standards and criteria for an acceptable category of continuing education under this rule and R 338.3044 and must be relevant to health care services, pharmacy operations, or advancement of the licensee's pharmacy education.

(d) A continuing education course or program shall be developed and presented by a sponsor and must provide all of the following:

(i) Availability of adequate records of participation.

(ii) Qualified teaching staff.

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(iii) A statement of educational objectives.

(e) Board approval is valid for 3 years from the date of approval.

(f) Except as provided in subdivision (g) of this subrule, any subsequent dates that the course or program will be offered do not require further board approval and may be changed without review by the board if the presentation dates are within the board's original 3-year term of approval.

(g) The board shall reevaluate an approved continuing education course or program before any changes during the approval term to the title, number of continuing education hours to be awarded to participants, or learning objectives.

(h) A sponsor conducting the course or program shall record all of the following on a continuing education certificate or other proof prepared by that sponsor:

(i) The name of the sponsor.

(ii) Continuing education approval number assigned by the department.

(iii) Course title or name of the program.

(iv) Name of the speaker or instructor.

(v) Date the approved course or program was conducted.

(vi) Number and type of continuing education hours awarded.

(vii) Approved sponsor's signature.

(viii) Dates of the current approval term.

(ix) Name of participant.

(i) The board may revoke the approval status of any approved course or program at any time if the course or program fails to comply with these 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	The number of hours earned will be the number of hours approved by the sponsor or the approving organization.		

	 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. 	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.
	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.	
(b)	Completion of postgraduate pharmacy practice or administration courses offered for credit in a pharmacy school accredited by the ACPE or the CCAPP.	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.
	If audited, a licensee shall submit an official transcript that reflects completion of the postgraduate pharmacy practice or administration course and number of semester or quarter credit hours earned.	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.	One hour will be earned for each hour devoted to a home study program. A maximum of 20 hours may be
	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.	earned per renewal period.
(d)	Participation as a preceptor for at least 1 pharmacy intern.	Five hours of continuing education may be earned for a minimum of 120 hours in person of precentorship in each renewal
	A preceptorship shall be for a minimum of 120 hours in person and have a 1 intern - to -	preceptorship in each renewal period.

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	1 preceptor ratio. This may involve multiple preceptor relationships at different times.	A maximum of 5 hours may be earned in each renewal period.
	If audited, a licensee shall submit written documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.	
(e)	Renewal of a pharmacy license held in	Thirty hours will be earned.
	another state that requires continuing education for license renewal that is	A maximum of 30 hours may be
	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.	earned in each renewal period.
	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	
(f)	held, or the activity was completed. Initial publication of an article or a chapter	Ten hours will be earned per
	related to the practice of pharmacy in either of the following:	publication.
	A pharmacy textbook.A peer reviewed journal.	A maximum of 10 hours may be earned in each renewal period.
	If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.	
(g)	Successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties (BPS).	Ten hours may be earned in the year in which the licensee achieves a passing score.
	If audited, a licensee shall submit proof of a passing score on the examination.	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.

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(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.	Two hours for every 50 minutes devoted to presenting the program. A maximum of 2 hours may be earned in each renewal period.
	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.	
(i)	Attendance at a pharmacy-related program that is approved by the board pursuant to R 338.3043.	The number of hours earned will be the number of hours approved by the sponsor or the approving organization.
1	 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. 	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)	Attendance at a full board of pharmacy meeting, disciplinary subcommittee meeting, or rules committee work group meeting.	One hour may be 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.

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FILED WITH SECRETARY OF STATE ON LO 200 23 AT 12:41 PM