



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

December 22, 2020

NOTICE OF FILING
ADMINISTRATIVE RULES

To: Secretary of the Senate
Clerk of the House of Representatives
Joint Committee on Administrative Rules
Michigan Office of Administrative Hearings and Rules (Administrative Rule #19-022-LR)
Legislative Service Bureau (Secretary of State Filing #20-12-09)
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 #2019-022-LR (Secretary of State Filing #20-12-09) on this date at 03:10 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(6) 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

Melissa Malerman, Departmental Supervisor
Office of the Great Seal

Enclosure



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

CERTIFICATE OF ADOPTION

By authority conferred on the Department of Licensing and Regulatory Affairs by Sections 16145, 16148, 16184, 16201, 16204, 16205, 17731, 17737, 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, 333.17737, 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R 338.3041, R 338.3043, and R 338.3044 of the Michigan Administrative Code are amended, and R 338.3045 is rescinded, to as follows:

Date: 12/21/2020

Adopted by:  _____

Orlene Hawks
Director
Department of Licensing and Regulatory Affairs



STATE OF MICHIGAN

GRETCHEN WHITMER
GOVERNOR

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

ORLENE HAWKS
DIRECTOR

LEGAL CERTIFICATION OF RULES

I certify that I have examined the attached administrative rules, dated July 31, 2020, 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.
- ◆ Rescinding R 338.3045.

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

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

Dated: August 10, 2020

Michigan Office of Administrative Hearings and Rules

By: 

Katie Wienczewski,
Attorney

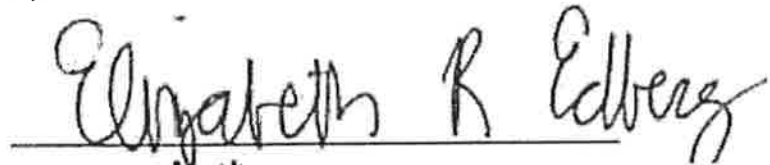
CERTIFICATE OF APPROVAL

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 July 31, 2020, amending R 338.3041, R 338.3043, and R 338.3044 and rescinding R 338.3045 of the Department's rules entitled "Pharmacy – Pharmacist Continuing Education." I approve the rules as to form, classification, and arrangement.

Dated: August 3, 2020

LEGISLATIVE SERVICE BUREAU

By



Elizabeth R. Edberg,
Legal Counsel

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PHARMACIST CONTINUING EDUCATION

Filed with the secretary of state on December 22, 2020

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) 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 department of licensing and regulatory affairs by sections 16145, 16148, 16184, 16201, 16204, 16205, 17731, 17737, 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, 333.17737, 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 338.3045 is rescinded, to read as follows:

R 338.3041 License renewals; continuing education requirements; applicability.

Rule 1. (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) An applicant for license renewal, who has been licensed for the 2-year period immediately preceding the end of the license cycle, 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 2 years immediately preceding the application for renewal, which must comply with all of the following:

(i) An applicant for license renewal shall complete at least 1 hour of the 30 required hours of continuing education in pharmacy ethics and jurisprudence. This paragraph applies only to renewals after December 30, 2020.

(ii) An applicant for license renewal shall complete a minimum of 10 hours of the 30 required hours of continuing education by attending live courses or programs that provide for direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops.

(iii) An applicant for license renewal shall complete 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(2). 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) An applicant for license renewal shall earn no more than 12 hours of continuing education during a 24-hour period.

(v) An applicant for license renewal shall not earn credit for taking the same continuing education course or program twice during 1 renewal period.

(2) 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(h).

(3) 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.

(4) 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.

(b) A completed application form shall be submitted to the department at least 70 days prior to the date the continuing education course or program is conducted and 70 days prior to the next regularly scheduled board meeting for the proposed continuing education to be considered for approval by the board. A continuing education course or program conducted prior to board consideration will not be approved.

(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 and advancement of the licensee's pharmacy education.

(d) A continuing education course or program must be a planned learning program designed to promote the continual development of knowledge, skills, and attitudes on the part of the pharmacist. The course or program must be an individual organized educational experience under responsible sponsorship and capable direction and must provide qualified instruction.

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

- (i) Administrative support that ensures maintenance and availability of adequate records of participation.
 - (ii) An adequate budget and resources.
 - (iii) Appropriate, qualified, competent teaching staff.
 - (iv) A statement of educational goals or measurable behavioral objectives, or both.
 - (v) Delivery methods that allow for active participation and involvement.
 - (vi) Appropriate, adequate facilities.
 - (vii) Evaluations of the participant and the provider.
- (f) The continuing education course or program must include study in 1 or more of the following subjects:
- (i) Social, psychological, economic, and legal aspects of health care delivery.
 - (ii) The properties and actions of drugs and dosage forms.
 - (iii) Etiology, characteristics, and therapeutics of the disease state.
 - (iv) Emergency skills related to the health and safety of the patient.
 - (v) Specialized professional services.
 - (vi) Other areas of study that the board finds are designed to maintain or enhance a pharmacist's ability to deliver competent pharmacy services.
- (g) Board approval is valid for a 3-year term of approval from the date of approval.
- (h) The board shall reevaluate an approved continuing education course or program prior to any changes during the approval term, including but not limited to, changes to either of the following:
- (i) Instructors and speakers.
 - (ii) Course or program content, title, and number of continuing education hours to be awarded to participants.
- (i) Subject to subdivision (j) of this rule, all changes to a previously approved course or program must be submitted on required department forms at least 70 days prior to the date the course or program is offered to participants and 70 days prior to the next regularly scheduled board meeting to be considered for approval by the board. Any changes to a submitted and previously approved course or program conducted prior to board reconsideration and approval will not be approved.
- (j) Emergency changes to instructors and speakers that cannot be submitted to the board at least 70 days prior to the date of the course or program may be reviewed by the department in consultation with the board chair or a continuing education board committee member if proof that is acceptable to the department and that supports the nature of the emergency is submitted with the change.
- (k) The specific 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.
- (l) 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.
 (m) The board may revoke the approval status of any approved course or program at any time 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		
(a)	<p>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:</p> <ul style="list-style-type: none"> • A pharmacy program accredited by the Accreditation Council for Pharmacy Education (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. <p>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.</p>	<p>The number of hours earned will be the number of hours approved by the sponsor or the approving organization.</p> <p>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.</p> <p>No limitation on the number of hours earned.</p>
(b)	<p>Completion of postgraduate pharmacy practice or administration courses offered for credit in a pharmacy school accredited by the ACPE or the CCAPP.</p> <p>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.</p>	<p>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.</p> <p>No limitation on the number of hours earned.</p>

(c)	<p>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.</p> <p>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.</p>	<p>One hour will be earned for each hour devoted to a home study program.</p> <p>A maximum of 20 hours per renewal period.</p>
(d)	<p>Participation as a preceptor for at least 1 pharmacy intern.</p> <p>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.</p> <p>If audited, a licensee shall submit written documentation from the educational institution or preceptor's supervisor verifying the dates and hours of the preceptorship.</p>	<p>Five hours of continuing education may be earned for a minimum of 120 hours in person of preceptorship in each renewal period.</p> <p>A maximum of 5 hours may be earned in each renewal period.</p>
(e)	<p>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.</p> <p>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, and the date on which the program was held or the activity was completed.</p>	<p>Thirty hours will be earned.</p> <p>A maximum of 30 hours may be earned in each renewal period.</p>
(f)	<p>Initial publication of an article or a chapter related to the practice of pharmacy in either of the following:</p> <ul style="list-style-type: none"> • A pharmacy textbook. • A peer reviewed journal. 	<p>Ten hours will be earned per publication.</p> <p>A maximum of 10 hours may be earned in each renewal period.</p>

	If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.	
(g)	<p>Successful completion of a board certification national pharmacy examination through Board of Pharmacy Specialties (BPS).</p> <p>If audited, a licensee shall submit proof of a passing score on the examination.</p>	<p>Ten hours may be earned in the year in which the licensee achieves a passing score.</p> <p>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.</p>
(h)	<p>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.</p> <p>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.</p>	<p>Two hours for every 50 minutes devoted to presenting the program.</p> <p>A maximum of 10 hours will be earned in each renewal period.</p>
(i)	<p>Attendance at a pharmacy-related program that is approved by the board pursuant to R 338.3043.</p> <p>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 course for continuing education credit, and the date on which the program was held or the activity was completed.</p>	<p>The number of hours earned will be the number of hours approved by the sponsor or the approving organization.</p> <p>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.</p> <p>No limitation on the number of hours earned.</p>

R 338.3045 Rescinded.