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From: Rose M Baran <RoseBaran@ferris.edu>
Sent: Wednesday, October 02, 2019 8:40 AM
To: BPL-BoardSupport
Cc: Ditschman, Andria (LARA)
Subject: Board of Pharmacy Rules Comment
Attachments: GeneralRulesCommentFinal.docx; CECComments10022019Final.docx

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing-Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170

Attention: Policy Analyst

Please find attached the comments on the Rules for the Board of Pharmacy - General Rules (ORR#2018-039 LR) and Board of Pharmacy - Pharmacist Continuing Education (ORR#2019-022LR).

Sincerely,
Rose Baran

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Comment on Board of Pharmacy Rules 2019 – 022 LR Pharmacist Continuing Education
Rose Baran Pharm. D.

Rule 338.3041 deletes the information on the number of CE hours required if licensed less than one year, greater than 1 year but less than 2 years. Does this mean that all new licenses will be issued for at least 2 years?

Rule 338.3041(1)(b) should be changed to read “For license renewals beginning in 2020, an applicant for license renewal shall have completed a 1-time training identifying victims of human trafficking.....”

The way it is currently written “Beginning with the first renewal cycle after November 13, 2017” is confusing on when the training is actually needed.

Rule 338.3041(1)(c) should be changed to read “For controlled substance license renewals beginning with the 2021 renewal cycles, an applicant for license renewal shall have completed a 1-time training in opioids and other controlled substances awareness.....”

The way it is currently written requires all pharmacists seeking renewal of their license to obtain the training while the training according to rule 338.3135 is only required for pharmacists seeking renewal of their controlled substance license. Also, the change makes it less confusing for the date it is required to start.

Rule 338.3041(d) requires the one hour in pharmacy ethics and jurisprudence be obtained to renew the license in 2020. That means the group of pharmacist renewing with the expiration date of June 30, 2020 will have less than 6 months to obtain this requirement. Would suggest changing the date, the start of rule 338.3041(d) to read “**Beginning in 2021.....**”

Or should rule 338.3041(1)(b) and (c) be completely eliminated as these requirements are not continuing education requirements but are licensing requirements. This is already addressed in rule 338.511 and rule 338.3135.

Rule 338.3041(d) changes “during the 2 year renewal period” to “2 years immediately preceding the application for renewal” does this mean if the license is issued for 26 months any continuing education done in months 1 and 2 would not count as continuing education for renewal?

Rule 338.3044(a) “**A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA).**” This should be changed to read “A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA) or Michigan Health and Hospital Association, or national pharmacy organizations, or health system.” This would allow for more entities to provide continuing education for pharmacists.



September 19, 2019

Andria M. Ditschman, JD,
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Dear Andria,

Thank you for allowing the Michigan Pharmacists Association (MPA) the opportunity to comment on the draft rules for Pharmacists Continuing Education Rules. We appreciate the Board of Pharmacy's willingness to work with all stakeholders and look forward to more open dialogue between us. Below are the Michigan Pharmacists Association's comments on the draft rules at this time.

R 338.3041 Rule 1 (1) "a special retired pharmacist's license" is not defined anywhere in statute or rules and needs to be.

R 338.3041 Rule 1 (d) add the words "upon request" after the word board, to make this rule more consistent with Rule 2.

R 338.3043 Rule 3 (iv) should read "Emergency skills related to the health and safety of the patient pharmacy."

R 338.3044 Rule 4 (a) MPA would like to note that pharmacy school ACPE/CCAPP accreditation process is not similar to ACPE accreditation for CE hours. The accreditation is based on different criteria. Recommend to remove the ACPE and CCAPP.

R338.3044 Rule 4 (b) Remove "18" and replace with "16."

R 338.3044 Rule 4 (f) Remove "10" and replace with "5."

R 338.3044 Rule 4 (h) The two hours for every 50 minutes does not align with ACPE and should be one hour for every 50 minutes.

If you have any questions please don't hesitate to contact me.

Thank you,
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DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

PHARMACY – PHARMACIST CONTINUING EDUCATION

Filed with the secretary of state on

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 ~~director of the department of community health~~ **department of licensing and regulatory affairs** by sections ~~16145(3), 16148, 16184, 16201, 16204, 16205, and 17731, 17737, and 17767~~ **of the public health code**, 1978 PA 368, MCL ~~333.16145(3) and , 333.16148, 333.16184, 333.16201, 333.16204, 333.16205, 333.17731, 333.17737, and 333.17767~~, et seq. and Executive Reorganization Order Numbers Nos. ~~1996-1 1991-9, 1996-2, and 2003-1, and 2011-4, being MCL 330.3101 338.3501, 445.2001, and 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 continuing** education requirements; applicability.

Rule 1. (1) These rules apply to applications for renewal of a pharmacist's license **and a special retired 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 renewal shall not be granted unless the applicant has fulfilled the requirements of these rules:**

(2) ~~An applicant who was originally licensed in Michigan less than 1 year before the renewal date is not required to comply with these rules.~~

(3) ~~An applicant who was originally licensed in Michigan more than 1 year but less than 2 years before the renewal date shall have accumulated 15 hours of continuing education credits pursuant to these rules. An applicant under this subrule shall be exempt from the requirement of subrule (5) of this rule.~~

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

(b) **Beginning with the first renewal cycle after November 13, 2017, 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**

Comment [FJ1]: Not defined in statute or rules

333.16148.

(4) Beginning with the first renewal cycle after January 4, 2019, an applicant for license renewal shall have completed a 1-time training in opioids and other controlled substances awareness as required in R 338.3135.

(5) (d) Except as otherwise provided in subrules (2) and (3) of this rule, Beginning in 2020, an applicant for license renewal, of a pharmacist's license 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 credits acceptable to approved by the board, as provided in under R 338.3043 and R 338.3044, during the 2-year renewal period 2 years immediately preceding the application for renewal, which must comply with all of the following: An applicant shall comply with subdivisions (5), (6) and (7) of this subrule. This subrule takes effect July 1, 2007.

Comment [F12]: The way that this is currently written, a licensee would have to send proof for renewal.

Suggested adding upon request to be more consistent with subrule (2) under this rule.

(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.

(6) (ii) An applicant for license renewal shall obtain complete a minimum of 10 hours of the 30 required hours of continuing education credits 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. This subrule takes effect July 1, 2007.

(7) (iii) An applicant for license renewal shall complete in each renewal period at least 1 hour of the 30 required hours of continuing education hour in pain and symptom management, as required under section 16204 16204(2) of the code, MCL 333.16204(2).- This subrule takes effect July 1, 2007. 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.

(8) (iv) An applicant for license renewal shall may not earn no more than 12 hours of continuing education in a day during a 24-hour period. This subrule takes effect July 1, 2007.

(9) Before applying to renew a license, an applicant shall possess certificates confirming continuing education credits awarded that are dated no later than the date the applicant submits the renewal application.

(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 ~~Education~~ **Continuing education** courses and programs; standards for approval.

Rule 3. ~~(1)~~ 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.

~~(2)~~ **(d) A continuing education course or program shall 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 shall must be an individual organized educational experience under responsible sponsorship and capable direction and shall must provide qualified instruction.**

~~(3)~~ **(e) A continuing education course or program shall be developed and presented by a sponsor and shall must provide all of the following:**

(a) (i) Administrative support which that ensures maintenance and availability of adequate records of participation.

(b) (ii) An adequate budget and resources.

(c) (iii) Appropriate, qualified, competent teaching staff.

~~(d)~~ **(iv) A statement of educational goals or measurable behavioral objectives, or both.**

(e) (v) Delivery methods that allow for active participation and involvement.

(f) (vi) Appropriate, adequate facilities.

(g) (vii) Evaluations of the participant and the provider.

~~(4) The accreditation council for pharmacy education (acpe) may certify a provider whose course or program was developed and presented in compliance with subrule (3) of this rule. The board may accept such certification as prima facie proof that a course or program meets the standards set forth in subrule (3) of this rule.~~

~~(5) A provider of a course or program that does not fall within subrule (4) of this rule may submit an application for approval. The application shall be submitted on a form~~

provided by the board.

(6) (f) A The continuing education course or program shall **must** include study in 1 or more of the following subjects:

- (a) (i) Social, psychological, economic, and legal aspects of health care delivery.
- (b) (ii) The properties and actions of drugs and dosage forms.
- (c) (iii) Etiology, characteristics, and therapeutics of the disease state.
- (d) (iv) Emergency skills **related to the health and safety of the patient**

pharmacy.

(e) (v) Specialized professional services.

(f) (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 Computation of credit hours Acceptable continuing education for licensees.

Rule 4. (1) If an organized continuing education course or program is offered in segments of 50 to 60 minutes each, 1 hour of credit shall be given for each such segment. A pharmacist shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period. For purposes of this rule, continuing education time shall exclude all of the following: Coffee breaks, Breakfast, lunch, or dinner breaks. Any other breaks in the program. The board shall consider all of the following as acceptable continuing education:

ACCEPTABLE CONTINUING EDUCATION ACTIVITIES

<p>(a)</p>	<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 school 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. • A continuing education sponsoring organization, institution, or individual approved by the Michigan Pharmacists Association (MPA). • 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>
<p>(b)</p>	<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>

Comment [F33]: MPA would like to note that pharmacy school ACPE/CCAPP accreditation process is not similar to ACPE accreditation for CE hours. The accreditation is based on different criteria.
Recommend to remove the ACPE and CCAPP.

Comment [F34]: For consistency – MPA recommends this changes to 16 hours.

(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 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 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</p>	<p>Ten hours will be earned per publication.</p>

Comment [FJ6]: MPA does not believe that the CE accredited through preceptorship should be considered Live CE.

Comment [FJ5]: A preceptor may not always have direct interaction with the student. Some student pharmacists may not interact with a preceptor at all. How will the board ensure that this will not be abused?
Consider removing.

Comment [FJ7]: MPA believes that 10 hours is excessive. Consider 5 hours
CE hours should be accredited as home study CE hour.

	<p>pharmacy in either of the following:</p> <ul style="list-style-type: none"> • A pharmacy textbook. • A peer reviewed journal. <p>If audited, a licensee shall submit a copy of the publication that identifies the licensee as the author or a publication acceptance letter.</p>	<p>A maximum of 5 hours may be earned in each renewal period.</p>
(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>

Comment [FJ9]: Does not align with ACPE

Comment [FJ8]: Clarification required: Will presenting the same presentation more than once grant the presenter additional CE hours?

(2) A pharmacist may earn 1 hour of continuing education credit for each hour devoted to 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, with a maximum of 20

~~continuing education hours obtained in each renewal period. A pharmacist shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period.~~

~~(3) Two hours of continuing education credit may be earned for each hour spent in actually presenting a course or program which has been approved for continuing education credit. A presenter shall not be granted multiple credit for the same program of continuing education in the same licensure renewal period.~~

~~(4) Twelve hours of continuing education credit may be earned for each 1 academic quarter-hour of postgraduate study of a course approved for continuing education credit given by an academic institution approved by the board.~~

~~(5) Eighteen hours of continuing education credit may be earned for each 1 academic semester-hour of postgraduate study of course approved for continuing education credit given by an academic institution approved by the board.~~

~~R 338.3045 Equivalents; pharmacists residing or practicing in other states. Rescinded. Rule 5. (1) An applicant for renewal who resided or practiced in another state that required substantially equivalent continuing education for renewal may obtain renewal of the Michigan license upon verification of licensure in the other state.~~

~~(2) An applicant for renewal who resided or practiced in another state that does not fall within subrule (1) may obtain renewal of the Michigan license upon proof that the applicant acquired continuing education substantially equivalent to that which is otherwise required by these rules.~~