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MEMORANDUM

TO: Christopher Harlow, Executive Director, Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:015, 201 KAR 002:030, 201 KAR 002:050, and 201 KAR 002:465.

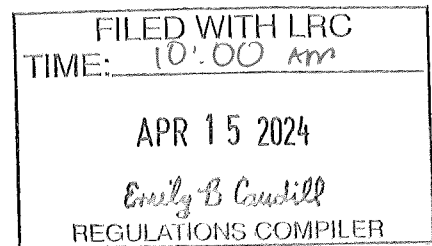
DATE: April 15, 2024

A copy of each administrative regulation listed above is enclosed for your files. These regulations are tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **JULY 2024** meeting. We will notify you of the date and time of this meeting once it has been scheduled.

Pursuant to KRS 13A.280, *if* comments are received during the public comment period, a Statement of Consideration or a one-month extension request for these regulations is due **by noon on JULY 15, 2024**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to the public hearing and public comment period and Statements of Consideration.

If you have questions, please contact us at RegsCompiler@LRC.ky.gov or (502) 564-8100.

Enclosures



1 GENERAL GOVERNMENT CABINET

2 Kentucky Board of Pharmacy

3 (Amendment)

4 201 KAR 2:015. Continuing education.

5 RELATES TO: KRS 315.010, 315.065, 315.120, 315.121

6 STATUTORY AUTHORITY: KRS 315.065, 315.110(1), 315.191(1)

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.065(2) and (3) require the
8 Board of Pharmacy to establish continuing education requirements for pharmacists. This
9 administrative regulation establishes requirements for the continuing pharmacy education
10 of registered pharmacists and requires all registered pharmacists holding a license issued
11 by the board to participate in continuing pharmacy education as a means of renewal of
12 their licenses.

13 Section 1. Definitions. (1) "Continuing education unit" or "CEU" is defined by KRS
14 315.010(8).

15 (2) "Sponsor" means a person, school, association, company, corporation, or group who
16 wishes to develop a continuing education program.

17 Section 2. (1) Continuing education hours for credit shall be relevant to the practice of
18 pharmacy and free of commercial bias.

- 1 (2) Continuing education hours shall be approved if approved by:
- 2 (a) The Accreditation Council for Pharmacy Education (ACPE); or
- 3 (b) The board.
- 4 Section 3. (1) Continuing education sponsors shall submit an Application for Provider CE
- 5 Approval to the board:
- 6 (a) At least sixty (60) days prior to the presentation date, if pre-approval is sought; or
- 7 (b) Between sixty (60) days prior and thirty (30) days after the presentation date, if pre-
- 8 approval is not sought.
- 9 (2) Program changes shall be submitted to and approved by the board, or the approval
- 10 of the program shall be void.
- 11 (3) Continuing education credit shall be given only once for each program per participant.
- 12 (4) Sponsors shall retain a file of each participant's program completion for three (3)
- 13 years.
- 14 (5) Board approval of each program shall expire three (3) years after the date of approval.
- 15 Section 4. (1) Pharmacists requesting approval of individually obtained continuing
- 16 pharmacy education shall submit an Application for Pharmacist CE Approval to the board
- 17 within thirty (30) days of completion of the educational presentation.
- 18 (2) The board shall notify the requesting pharmacist whether the application request has
- 19 been approved or denied.
- 20 (3) Continuing education that has not been approved by ACPE or the board shall not be
- 21 used to meet continuing education requirements for renewal or issuance of a license.
- 22 Section 5. (1) A pharmacist shall:

- 1 (a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours)
2 annually between March 1 and February 28 of the subsequent year prior to licensing
3 renewal [~~January 1 and December 31~~]; and
- 4 (b) For licensing years 2023 through 2028, one contact hour of the fifteen (15) contact
5 hours shall be on the opioid epidemic or opioid use disorder; and
- 6 (c) Not transfer or apply excess hours or units for future years.
- 7 (2) A pharmacist may be granted a deferral on a year-to-year basis at the determination
8 of the board for illness, incapacity, or other extenuating circumstances.
- 9 (3) A pharmacist first licensed by the board within twelve (12) months immediately
10 preceding the annual renewal date shall be exempt from the continuing pharmacy
11 education provisions for that year.
- 12 (4) Pharmacists shall:
- 13 (a) Keep valid records, receipts, and certifications of continuing pharmacy education
14 programs completed for three (3) years; and
- 15 (b) Submit that documentation to the board upon request.
- 16 (5) Submission of a fraudulent statement or certificate concerning continuing pharmacy
17 education shall subject the pharmacist to discipline as provided in KRS 315.121.
- 18 Section 6. Each pharmacist shall keep the board informed of the pharmacist's correct
19 address.
- 20 Section 7. CEU may be transferred from another state to Kentucky if the transfer state
21 recognizes Kentucky CEU.
- 22 Section 8. A licensee who failed to timely renew his or her license shall:
- 23 (1) Comply with the applicable provisions of KRS 315.120(2) or (3); and

1 (2) Complete fifteen (15) hours of continuing education for each year the applicant failed
2 to renew his or her license, up to a maximum of seventy-five (75) hours.

3 Section 9. Incorporation by Reference. (1) The following material is incorporated by
4 reference:

5 (a) The "Application for Provider CE Approval", June 2018; and.

6 (b) The "Application for Pharmacist CE Approval", June 2018.

7 (22) This material may be inspected, copied, or obtained, subject to applicable copyright
8 law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort,
9 Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m or on the Web site at
10 <https://pharmacy.ky.gov/professionals/Pages/Continuing-Education-.aspx>

Chilton

Christopher Harlow, Pharm.D.
Executive Director
Board of Pharmacy

April 15, 2024

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on June 25, 2024, at 10:00 a.m. Eastern Time via zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through June 30, 2024. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

Contact person: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

201 KAR 2:015. Continuing education.
Contact person: Christopher Harlow
Contact Phone No.: 502-564-7910
Contact email: christopher.harlow@ky.gov

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation establishes continuing education requirements.
- (b) The necessity of this administrative regulation: KRS 315.065(2) and (3) requires the board to promulgate a regulation that includes guidelines and criteria for reviewing and approving acceptable continuing education programs.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This regulation establishes guidelines and criteria for reviewing and approving acceptable continuing education programs as required by KRS 315.065(2) and (3).
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Pharmacists will understand continuing education requirements necessary for renewal of licenses.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

- (a) How the amendment will change this existing administrative regulation: The amendment changes the period of time in which CE hours are to be acquired to help streamline licensees ability to track CE in line with the requirements in other states.
- (b) The necessity of the amendment to this administrative regulation: To assist pharmacists in tracking their CE obligation for Kentucky.
- (c) How the amendment conforms to the content of the authorizing statutes: KRS 315.065(2) and (3) requires the board to promulgate a regulation that includes guidelines and criteria for reviewing and approving acceptable continuing education programs; the amendment assists pharmacists with tracking their annual continuing education.
- (d) How the amendment will assist in the effective administration of the statutes: The amendment will ensure pharmacists can track their CE obligations for Kentucky because the requirements will align with that in other states.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Only pharmacists will be impacted by this regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

- (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacists will need to ensure that they familiarize themselves with the new period. Moreover, the Board will offer enforcement discretion for a period of time to assist with this.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for those identified in question (3).
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Pharmacists will receive continuing education credit required for renewal.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

- (a) Initially: No costs will be incurred.
- (b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacists.

FISCAL IMPACT STATEMENT

Regulation No. 201 KAR 2:015. Continuing education

Contact Person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1) and KRS 315.065.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:
The Kentucky Board of Pharmacy

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? There will be no expenditures or cost savings.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): None, only the Kentucky Board of Pharmacy is impacted.

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This regulation does not create any expenditures, revenues or cost savings.

(4) Identify additional regulated entities not listed in questions (2) or (3): none.

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This regulation does not create any expenditures, revenues or cost savings.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: There is no fiscal impact from this regulation.

(b) Methodology and resources used to determine the fiscal impact: There are no fees or costs associated with this regulation.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate). This administrative regulation will not have an overall negative or adverse major economic impact to the entities identified.

(b) The methodology and resources used to reach this conclusion: There are no costs, expenditures or revenues from this regulation.

Summary of Material Incorporated by Reference

“APPLICATION FOR PROVIDER CE APPROVAL,” dated June 2018, is a 2-page document that contains the information required for the Board to consider approving continuing education submitted by a sponsor.

“APPLICATION FOR PHARMACIST CE APPROVAL,” dated June 2018, is a 2-page document that contains the information required for the Board to consider approving continuing education submitted by a pharmacist.

