MEMORANDUM

TO: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:015, 201 KAR 002:020, 201 KAR 050 & 201 KAR 002:225

DATE: April 4, 2022

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 2022 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, 2022. 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
GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:015. Continuing education.

RELATES TO: KRS 315.065, 315.120

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

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

Section 1. Definitions. (1) "Continuing education unit" or "CEU" is defined by KRS 315.010(7).

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

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

(2) Continuing education hours shall be approved if approved by:

(a) The Accreditation Council for Pharmacy Education (ACPE); or

(b) The board.

Section 3. (1) Continuing education sponsors shall submit an Application for Provider CE Approval to the board:
(a) At least sixty (60) days prior to the presentation date, if pre-approval is sought; or

(b) Between sixty (60) days prior and thirty (30) days after the presentation date, if pre-approval is not sought.

(2) Program changes shall be submitted to and approved by the board, or the approval of the program shall be void.

(3) Continuing education credit shall be given only once for each program per participant.

(4) Sponsors shall retain a file of each participant’s program completion for three (3) years.

(5) Board approval of each program shall expire three (3) years after the date of approval.

Section 4. (1) Pharmacists requesting approval of individually obtained continuing pharmacy education shall submit an Application for Pharmacist CE Approval to the board within thirty (30) days of completion of the educational presentation.

(2) The board shall notify the requesting pharmacist whether the application request has been approved or denied.

(3) Continuing education that has not been approved by ACPE or the board shall not be used to meet continuing education requirements for renewal or issuance of a license.

Section 5. (1) A pharmacist shall:

(a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between January 1 and December 31; and

(b) For licensing years 2023 through 2028, one contact hour of the fifteen (15) contact hours shall be on the opioid epidemic or opioid use disorder.

(c) Not transfer or apply excess hours or units for future years.

(2) A pharmacist may be granted a deferral on a year-to-year basis at the discretion of the board for illness, incapacity, or other extenuating circumstances.
(3) A pharmacist first licensed by the board within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions for that year.

(4) Pharmacists shall:

(a) Keep valid records, receipts, and certifications of continuing pharmacy education programs completed for three (3) years; and

(b) Submit that documentation to the board on request.

(5) Submission of a fraudulent statement or certificate concerning continuing pharmacy education shall subject the pharmacist to discipline as provided in KRS 315.121.

Section 6. All pharmacists shall keep the board informed of their correct addresses.

Section 7. CEU may be transferred from another state to Kentucky if the transfer state recognizes Kentucky CEU.

Section 8. A licensee who failed to timely renew his or her license shall:

(1) Comply with the applicable provisions of KRS 315.120(2) or (3); and

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


(2) The “Application for Pharmacist CE Approval”, June 2018, is incorporated by reference.

(3) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
Christopher Harlow, Pharm.D.
Executive Director
Kentucky Board of Pharmacy
PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on June 22, 2022 at 9 a.m. at the Board’s office, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601 and via zoom teleconference. Individuals interested in attending this hearing shall notify this agency in writing five workdays prior to this hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled.

This hearing is open to the public. Any person 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 attend the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through June 30, 2022.

Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601; Telephone No. (502) 564-7910; Facsimile No. (502) 696-3806; 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 specifies that one hour of each licensing period’s continuing education must be on the opioid epidemic or opioid use disorder.

(b) The necessity of the amendment to this administrative regulation: Due to the increasing rates of opioid use disorder, pharmacists need to have this knowledge to adequately counsel patients and understand treatments.

(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 amendments does create a new one hour guideline.

(d) How the amendment will assist in the effective administration of the statutes: The amendments will help pharmacists to better understand the opioid epidemic and will prepare them to adequately counsel patients and understand possible treatment options.

(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 one hour of each yearly continuing education licensing requirements be on the topic of the opioid epidemic or opioid use disorder.

(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 the identities 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 NOTE ON STATE OR LOCAL GOVERNMENT

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. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.065(3) requires the board to establish continuing education requirements.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the board in the first year.

   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the board in subsequent years.

   (c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

   (d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): 0
Expenditures (+/-): 0
Other Explanation:
“APPLICATION FOR PROVIDER CE APPROVAL,” dated June 2018, is a 1-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 1-page document that contains the information required for the Board to consider approving continuing education submitted by a pharmacist.
APPLICATION FOR PROVIDER CE APPROVAL

For providers seeking pre-authorization, the application form must be received at least 60 days preceding the presentation. Application form must be submitted within 60 days preceding through 30 days following presentation for approval. Form and supplemental documentation may be mailed, emailed or faxed. Illegible or incomplete submissions will be returned. The board reserves the right to deny approval of any request. The request must be free of commercial bias.

Application Date Submitted ________________  Presentation Date[s] ________________

Name of Provider/Sponsor/Organization/Institution

________________________________________________________________________

Address ______________________________________________________________________

Phone Number ______________________________________________________________________

Email address of Provider/Sponsor ______________________________________________________________________

Presenters/CE Coordinators name ______________________________________________________________________

Presenter’s Address ______________________________________________________________________

________________________________________________________________________

Presenter’s Phone Number ______________________________________________________________________

Presenter’s Email address ______________________________________________________________________

Please enclose copy of the Presenter’s resume/credentials/title.

Name of Continuing Education

Number of credit hours being requested ______________________________________________________________________

List of CE Goals and Objectives (use additional paper if necessary)

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Please include a copy of the power point or a complete handout of the desired program.

Revised June 2018
APPLICATION FOR PHARMACIST CE APPROVAL

No program will be approved past 30 days of program presentation. Form and supplemental documentation may be mailed, emailed or faxed. Illegible or incomplete submissions will be returned. The board reserves the right to deny approval of any request. The request should be free commercial bias.

Application Date Submitted
For each individual program, please complete the following:

Presentation Date[s]    

Pharmacist name
Address
Phone Number
License Number       NABP e-Profile ID

Name of Provider/Sponsor/Organization/Institution

Address
Phone Number
Email address of Provider/Sponsor

Presenters/CE Coordinators name
Presenter’s credentials/title.

Name of Continuing Education
Number of credit hours being requested
List of CE Goals and Objectives (use additional paper if necessary)

Please include a copy of the power point or a complete handout of the desired program.

Revised June 2018