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
BOARD AND COMMISSIONS [JUSTICE AND PUBLIC SAFETY]

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:020 Examination.

RELATES TO: KRS 218A.205(7), 315.050

STATUTORY AUTHORITY: KRS 218A.205(7), 315.050(2), 315.191(1), (2), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(2) and 315.191(1)(c)

authorize the board to promulgate administrative regulations to prescribe the time, place,
method, manner, scope, and subjects of examinations. KRS 218A.205 (7) requires the board to
establish requirements for background checks for licensees. This administrative regulation
establishes the examination and application requirements for obtaining a license to practice
pharmacy in Kentucky.

Section 1. The examination for licensure shall include:

(1) The North American Pharmacist Licensure Examination (NAPLEX); and

(2) The Multistate Pharmacy Jurisprudence Examination (MPJE).

Section 2. Both the NAPLEX and the MPJE examinations are graded as pass or fail. [The
passing score on the required examinations shall be:

(1) At least seventy-five (75) on the basis of the NAPLEX and the MPJE grades shall not be used
in computing the NAPLEX; and
Section 3. If an applicant fails an examination [to obtain the necessary scores in any of the tests] described in Section 2 of this administrative regulation, the applicant may upon proper application retake the examination [tests upon the payment of the fee set forth in 201 KAR 2:050 plus any direct costs for test materials and supplies]. An applicant is limited to three attempts for each examination without further board approval. An applicant is limited to a lifetime limit of five (5) attempts on each examination [who has failed any test may retake that test within one (1) year of the date the applicant first failed the test without having to reapply].

Section 4. If after three examination attempts, the applicant has not passed, to qualify for two additional attempts, the applicant must:

(1) For the NAPLEX, complete a refresher course and submit to the Board of Pharmacy a certificate of completion; and

(2) For the MPJE, submit to the Board of Pharmacy:

a. Proof of (5) five hours of ACPE or Board approved continuing education in the topic of pharmacy law, or

b. A certificate of completion of a refresher course.

Section 5. All results of examinations shall be preserved according to the Board of Pharmacy Record Retention Schedule.

Section 6. [Fees submitted with an application shall be nonrefundable.

Section 6.] Prior to approval for examination, an applicant shall:
(1) Submit to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and

(2) Submit to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

(3) Submit an initial application for pharmacist licensure that reports:

   a. Name, maiden, and other names used currently or previously;

   b. Address and telephone number;

   c. Date of birth;

   d. Social Security number;

   e. Citizenship;

   f. Sex;

   g. Name of pharmacy school;

   h. Intern Registration Number;

   i. Record of any conviction for any felony or misdemeanor offense;

   j. Record of any state licensing agency refusal of licensure, failure of examination or refusal of examination; and

   k. Certificate of moral standing.

(4) Submit a certification of pharmacy school graduation;

(5) Submit a certification of intern hours.
Section 7. [License, ] Fee. An applicant shall submit[):

1. An Initial Application for Pharmacist Licensure pursuant to KRS 315.050; and
2. As appropriate[,] the fee established by 201 KAR 2:050, Section 1(1).

Section 8. Incorporation by Reference.

2. "Certification of College Graduation", Form 2, 03/2022 is incorporated by reference.
3. "Certification of Intern Hours", Form 3, 03/2022 is incorporated by reference.
4. This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday 8:00 a.m. to 4:30 p.m.
Christopher P. Harlow
Executive Director
Kentucky Board of Pharmacy

April 4, 2022
Date
PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on June 22, 2022 at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601. 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, 2022. 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 P. 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 2:020 Examination.
Contact person: Christopher P. Harlow, Phone 502-564-7910, email Christopher.Harlow@ky.gov

(1) Provide a brief summary of:
   (a) What this administrative regulation does: This administrative regulation establishes the requirements for the examinations

   (b) The necessity of this administrative regulation: KRS 315.050(2) and 315.191(1)(c) authorizes the Board of Pharmacy to promulgate administrative regulations to prescribe the time, place, method, manner, scope, and subjects of examinations. KRS 218(A)205(7) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes the examination and application requirements for obtaining a license to practice pharmacy in Kentucky.

   (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the examination and application requirements for obtaining a license to practice pharmacy in Kentucky.

   (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Incorporate by reference new initial pharmacist application for licensure.

(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: Retitle this regulation; Updates language on how scores are reported to the Board of Pharmacy. Establishes limits on the number of attempts a candidate may take the exams. Adds requirements for requesting multiple attempts to an examination.

   (b) The necessity of the amendment to this administrative regulation: The criteria needed to be updated based on score reporting by the agency that administers the examination. Adding limits to the examination protects the integrity of the examination and provides the Board of Pharmacy the ability to certify additional training for unsuccessful attempts.

   (c) How the amendment conforms to the content of the authorizing statutes: KRS 315.050(2) and 315.191(1)(c) authorizes the Board of Pharmacy to promulgate administrative regulations to prescribe the time, place, method, manner, scope, and subjects of examinations.

   (d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists by ensuring appropriate licensing standards.
(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(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: Pharmacist applicants will have to familiarize themselves with amended language. The board will help to educate pharmacist applicants in these changes.

(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 new costs for the identities to comply with the amendment except multiple failed attempts would require additional training which may insure some cost.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This will provide better integrity of the examination process for all applicants.

(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 applicants desiring to apply for Kentucky pharmacist licensure.
FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

201 KAR 2:020 Examination.
Contact Person: Christopher P. Harlow, Phone 502-564-7910, 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 the only entity 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 315.050(2).

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:
Summary of Material Incorporated by Reference

The “Initial Application for Pharmacist Licensure” is the 3-page initial application form that pharmacist are required to file before engaging in the practice of pharmacy. KRS Chapter 315.030 requires pharmacist to complete a licensure application by the Board of Pharmacy. Form 1 – 1/2012 has been updated to Form 1 – 03/2022 by removing the need for a photograph, and removed question 11, “Have any changes involving moral turpitude or violation of pharmacy, liquor, or dug laws ever been made against you”.

The “Certification of College Graduation”, Form 2, 03/2022 has been added to verify graduation from a college of pharmacy.

The “Certification of Intern Hours”, Form 3, 03/2022 has been added to certify completion of the required pharmacist intern hours.
Optional Demographic Information

Race/Ethnic Group (check one):

☐ Caucasian  ☐ Hispanic
☐ Asian  ☐ African American
☐ American Indian or Alaskan Native
☐ Other ______________________

Form 1-03/2022

Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, Kentucky 40601
Phone: 502-564-7910
Fax: 502-696-3806

Initial Application for Pharmacist Licensure

This application and fee of $150 must be in the Board Office before taking the NAPLEX or MPJE. Answer all questions in full and print legibly. Please make checks payable to the ‘Kentucky State Treasurer’.

I hereby make application for examination by the Kentucky Board of Pharmacy for license as a Pharmacist in Kentucky subject to the provisions of the statues and rules and regulations of the Board and being duly sworn submit the following:

1. Name: ________________________________________________________________

2. Address: __________________________________________________________________________________

3. ________________________________________________________________________________________________
   Street and Number

4. Telephone Number (     ) ______-_________  5. E-mail Address: ________________________________
   (Where you can be reached prior to examination)

6. Date of Birth ____________________________ 7. Sex (check one):  ☐ Male  ☐ Female

8. Social Security No. ______________________

9. Kentucky Pharmacist Intern Registration Number ______________________

10. Please provide the name of the College of Pharmacy you attended ________________________________

11. Have you ever been convicted of a misdemeanor?  ____No  ____Yes  A felony?  ____No  ____Yes

   If yes, give details:
   _______________________________________________________________________________________________
   _______________________________________________________________________________________________
   (If additional space is needed for details, please attach separate sheet)

12. Have you ever failed or been refused an examination by any State Board of Pharmacy or other state licensing agency?  _______No  _______Yes  If yes, give details:
   _______________________________________________________________________________________________
   _______________________________________________________________________________________________
   (If additional space is needed for details, please attach separate sheet)

13. Have you ever been refused licensure by any State Board of Pharmacy or other state licensing agency?  
    _______No  _______Yes  If yes, give details:
    _______________________________________________________________________________________________
    _______________________________________________________________________________________________
    (If additional space is needed for details, please attach separate sheet)

License No. ________
Date Issued ________
NAPLEX Score ________
MPJE Score ________

(FOR OFFICE USE ONLY)

Form 1-03/2022
14. Have you ever had a Certification of Registration as a Pharmacist suspended, probated, or revoked by any State Board of Pharmacy? __________ No __________ Yes If yes, give details:

____________________________________________________________________________________________
_____________________________________________________________________________________________

(If additional space is needed for details, please attach separate sheet)

I certify that the statements contained in this application are true, complete, and correct, and I agree that the statements shall form the basis of my application and I do authorize the Kentucky Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may now or in the future have concerning me to any person, corporation, institution, association, Board or any municipal, county, state, or federal governmental agencies or units, and that I understand according to the Kentucky Revised Statutes a Pharmacist’s License may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit.

Signature in Full

____________________________________________________________________________________________

I hereby certify that the above application was signed, subscribed and sworn to before me this ____ day of ______________, 20__.

(Seal)

Signature _________________________________

My commission expires _____________________ State of _____________________________________________

This certificate of moral character must be signed by a person of good standing in the community in which the applicant resides.

I, ____________________________________________ of _____________________________ do say that the applicant herein named, has been personally known to me for _______ years, that my acquaintance with the applicant throughout that period has been sufficiently intimate to afford me ample opportunity to become fully informed as to the applicant’s moral character and habits, that the applicant is not addicted to the use of alcoholic liquors or drugs so as to render the applicant unfit to practice Pharmacy, that the applicant is of good moral character and that I recommend the applicant, so far as character and habits are concerned, as worthy to be licensed to practice Pharmacy in Kentucky.

_________________________________________        _________________________________________________
(Date)                                           (Signature)

_______________________________________________
(Occupation)
CERTIFICATION OF COLLEGE GRADUATION

[To be executed by the Dean of the College of Pharmacy where the applicant attended Pharmacy School.]

Please make a copy of this section and submit to the Dean of the College of Pharmacy where you graduated for completion. Please indicate below the College of Pharmacy attended.

This is to certify that ____________________________ was in regular attendance at ____________________________________________ and that a certificate of graduation with the degree ____________________________ was conferred on ____________________________.

____________________________________
(SEAL)

____________________________________________________________________
(Signature)

____________________________________________________________________
(Title)

____________________________________________________________________
(Date)
CERTIFICATION OF INTERN HOURS

Please make a copy of this section and submit to the appropriate person[s] of the College of Pharmacy where you graduated or the State Board of Pharmacy if hours are outside of Kentucky for completion.

If certifying agency is the College of Pharmacy, please complete section A.

[A] This is to certify that ________________________________, was in regular attendance at _______________________________ and that ________ hours were accrued during rotations.

If certifying agency is a State Board of Pharmacy, please complete section B.

[B] This is to certify that ________________________________, while an intern with the _______________________________ earned ________ hours.

____________________________________
(SEAL)

____________________________________
(Signature)

____________________________________
(Title)

____________________________________
(Date)

The Kentucky Board of Pharmacy does not discriminate on the basis of race, color, national origin, sex, religion, age or disability in employment or the provision of services and provides, upon request, reasonable accommodation, including auxiliary aids and services, necessary to afford individuals with disabilities an equal opportunity to participate in all programs and activities. Contact the Board for assistance.