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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.

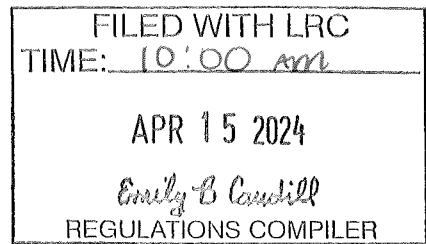
DATE: April 15, 2024

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 2:050. Licenses and permits; fees.

5 RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1),

6 315.050(5), 315.060, 315.110, 315.120, 315.191, 315.402

7 STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.036(1),

8 315.050(5), 315.060, 315.110(1), 315.120(4), 315.191(1)(i), 315.402(1)

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the board to assess
10 reasonable fees for services rendered to perform its duties and responsibilities. This administrative
11 regulation establishes reasonable fees for the board to perform all the functions for which it is
12 responsible.

13 Section 1. The following fees shall be paid in connection with pharmacist examinations and
14 licenses, pharmacy permits, intern certificates, and the issuance and renewal of licenses and
15 permits:

16 (1) Application for initial pharmacist license - \$150;

17 (2) Application and initial license for a pharmacist license by license transfer - \$250;

18 (3) Annual renewal of a pharmacist license - ninety-five (95) dollars;

19 (4) Delinquent renewal penalty for a pharmacist license - ninety-five (95) dollars;

20 (5) Annual renewal of an inactive pharmacist license - ten (10) dollars;

21 (6) Pharmacy intern certificate valid six (6) years - twenty-five (25) dollars;

22 (7) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;

- 1 (8) Application for a permit to operate a pharmacy - \$150;
- 2 (9) Renewal of a permit to operate a pharmacy - \$150;
- 3 (10) Delinquent renewal penalty for a permit to operate a pharmacy - \$150 dollars;
- 4 (11) Change of location or change of ownership of a pharmacy or manufacturer permit - \$150;
- 5 (12) Application for a permit to operate as a manufacturer - \$150;
- 6 (13) Renewal of a permit to operate as a manufacturer - \$150;
- 7 (14) Delinquent renewal penalty for a permit to operate as a manufacturer - \$150;
- 8 (15) Change of location or change of ownership of a wholesale distributor license - \$150;
- 9 (16) Application for a license to operate as a wholesale distributor - \$150;
- 10 (17) Renewal of a license to operate as a wholesale distributor - \$150;
- 11 (18) Delinquent renewal penalty for a license to operate as a wholesale distributor -\$150;[-and]
- 12 (19) Query to the National Practitioner Data Bank of the United States Department of Health
- 13 and Human Services - twenty-five (25) dollars;
- 14 (20) Application for non-resident pharmacist license - fifty (50) dollars;
- 15 (21) Renewal for non-resident pharmacist license - fifty (50) dollars; and
- 16 (22) Delinquent renewal penalty for non-resident pharmacist license - fifty (50) dollars.

17 Section 2. A pharmacy permit applicant[~~An applicant~~] shall submit:

- 18 (1) An initial or renewal application for a pharmacy permit on either the:
 - 19 (a)
 - 20 1. Application for Permit to Operate a Pharmacy in Kentucky; or
 - 21 2. Application for Resident Pharmacy Permit Renewal; or
 - 22 (b)
 - 23 1. Application for Non-Resident Pharmacy Permit, as incorporated into 201 KAR 2:465; or
 - 24 2. Application for Non-Resident Pharmacy Permit Renewal, as incorporated into 201 KAR 2:465;
- 25 and

1 (2) As appropriate, the:

2 (a) Initial application fee established by Section 1(8) of this administrative regulation; or

3 (b) Renewal fee established by Section 1(9) of this administrative regulation.

4 Section 3. All fees shall be non-refundable.

5 Section 4. Applications shall expire one (1) year after the date the application is received by the
6 Board.

7 Section 5. Incorporation by Reference.

8 (1) The following material is incorporated by reference:

9 (a) [~~"Application for Non-Resident Pharmacy Permit", Form 3, 9/2023;~~

10 (b) [~~"Application for Non-Resident Pharmacy Permit Renewal", Form 4, 9/2023;~~

11 (e)] "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, 6/2023; and

12 (b)[~~(d)] "Application for Resident Pharmacy Permit Renewal", Form 2, 6/2023.~~

13 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the

14 Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street,

15 Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

16 This material is also available on the board's Web site at

17 <https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx>.

Chris Harlow

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 2:050 Licenses and Permits; fees. 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 the fees associated with Board of Pharmacy licensure.

(b) The necessity of this administrative regulation: KRS 315.191(1)(i) authorizes the Board of Pharmacy to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is responsible.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes reasonable fees for the operating costs to ensure that the board performs all functions as detailed in KRS 315.191(1) including regulating and controlling pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers, to the extent that regulation and control of same have not been delegated to another agency.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation allows for the funding to support Board administration.

(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 adds additional fees for the category of non-resident pharmacist license, non-resident pharmacist license renewal, delinquent renewal penalty for non-resident pharmacist licensure, and this amendment clarifies that applications expire after one year and that all fees received are non-refundable.

(b) The necessity of the amendment to this administrative regulation: This administrative regulation is necessary to ensure the Board is adequately protecting the residents of the Commonwealth. The new fees created are for application in an amendment to 201 KAR 2:030 in which the Board seeks to license non-resident pharmacists that dispense prescription drugs to residents of the Commonwealth. Licensing these pharmacists will provide the Board with jurisdiction to adequately monitor and discipline these pharmacists should they violate Kentucky law when providing care to Kentucky patients.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(i) authorizes the Board of Pharmacy to assess reasonable fees for services rendered to perform its duties and responsibilities. KRS 315.005 states that the Board's purpose is to promote, preserve, and protect public health, safety, and welfare by and through effective control and regulation of all sites or persons, whether located in or outside the Commonwealth that distribute or sell drugs within the Commonwealth.

(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 that are dispensing prescription drugs to Kentucky patients.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Regarding the amendment related to non-resident licensure, non-resident pharmacists will be impacted by the new fees in this regulation. Should the pharmacy wish to pay the non-resident licensure fee for all their pharmacists in aggregate, the pharmacy would be impacted. All licensees and permit holders are impacted by this regulation because this regulation establishes the fee structure for all the board's licensees and permit holders. Those fees support all operating costs of the Board.

(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: Non-resident pharmacists that are currently dispensing prescription drugs into the Commonwealth for Kentucky patients that are not already licensed in Kentucky will need to become licensed in Kentucky pursuant to the rules established in the amendment to 201 KAR 2:030.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The fee for non-resident pharmacist licenses is fifty dollars.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): These licensees will have the ability to dispense prescriptions into Kentucky, enabling access to a larger patient population.

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

(a) Initially:

(b) On a continuing basis:

Other explanation: This regulation contains fees that are already in effect. The only new fees are those regarding non-resident licensure. Those licenses will be maintained by the Board and the cost of which is detailed in our fiscal statement.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from 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: This amendment creates a new category of fee for non-resident pharmacists dispensing prescription drugs into Kentucky. That is the only category in this regulation that has been added and is not currently already rule.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This amendment does create new categories of fees for non-resident pharmacist licenses. That fee is \$50.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacies, wholesale distributors, manufacturers, pharmacists and interns.

FISCAL IMPACT STATEMENT

Regulation No. 201 KAR 2:050. Licenses and permits; fees Contact Person: Christopher 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 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 315.191(1)(a).

(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 serves as the primary revenue source for the board. This administrative regulation is estimated to generate approximately \$2,730,000 in fiscal year 2024- 2025 without the addition of non-resident licenses issued. The estimate for issuance of non- resident licenses is estimated to add \$462,500. This estimate is based on the estimated revenue generated for the BFY 2024-2025 and data collected from non-resident pharmacies indicating the number of pharmacists dispensing prescriptions to residents of the Commonwealth without a licensed issued by the Kentucky Board of Pharmacy.

(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 generate approximately \$3,312,500 each year subsequently. This revenue is used for all operating expenditures of the board and is estimated based on the estimated revenue generated for the BFY 2025-2026 and data collected from non- resident pharmacies indicating the number of pharmacists dispensing prescriptions to residents of the Commonwealth without a license issued by the Kentucky Board of Pharmacy.

(c) How much will it cost to administer this program for the first year? The Kentucky Board of Pharmacy is implementing a new licensing management software in 2024. The cost associated with this new software included the proposed changes with this amended regulation. The base price for the software is \$220,500 plus the implementation cost of \$88,200. The year 1 support and maintenance is \$66,150. This fund has been appropriated to the Kentucky Board of Pharmacy by the passing of HB6 in 2024. Additional administrative costs to administer the proposed amendment includes personnel for licensing pharmacists and non-resident pharmacies. The Kentucky Board of Pharmacy estimates the annual and ongoing personnel cost to be \$132,000. The budget allocated to the Kentucky Board of Pharmacy to cover all operating expenditures for BFY 2024-2025 is \$3,268,700.

(d) How much will it cost to administer this program for subsequent years? The year 2-5 support and maintenance for the licensing management software ranges from \$66,150 to \$72,284.

Additional administrative cost to administer the proposed amendment includes personnel for licensing pharmacists and non-resident pharmacies. The Kentucky Board of Pharmacy estimates the annual and ongoing personnel cost to be \$132,000. The budget allocated for the Kentucky Board of Pharmacy to cover all operating expenditures for BFY 2025-2026 is \$3,328,800.

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

Revenues (+/-) \$3,192,500:

Expenditures (+/-) \$3,268,700:

Other Explanation: n/a

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? This regulation is not anticipating to provide any cost savings to regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? This regulation is not anticipating to provide any cost savings to regulated entities.

(c) How much will it cost the regulated entities for the first year? The estimated cost to regulated entities will depend on which category the regulated entity falls into.

(d) How much will it cost the regulated entities for subsequent years? The estimated cost to regulated entities will depend on which category the regulated entity falls into.

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

Cost Savings (+/-): 0 Expenditures (+/-):

Other Explanation: This regulation establishes fees to individuals and facilities regulated by the Kentucky Board of Pharmacy. The fees established provide a funding source for the board to achieve its mission to promote, preserve, and protect the public health, safety, and welfare for the people of the Commonwealth of Kentucky.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: This regulation establishes fees to individuals and facilities regulated by the Kentucky Board of Pharmacy. The fees established provide a funding source for the board to achieve its mission to promote, preserve, and protect the public health, safety, and welfare for the people of the Commonwealth of Kentucky.

(b) Methodology and resources used to determine the fiscal impact: The estimates provided were based on historical revenues and expenditures. For the proposed amendment, data was collected from non-resident pharmacies indicating the number of pharmacists dispensing

prescriptions to residents of the Commonwealth without a license issued by the Kentucky Board of Pharmacy.

(6) Explain:

(a) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does have major economic impact.

(b) The methodology and resources used to reach this conclusion: This regulation serves as the primary funding source for the Kentucky Board of Pharmacy. The estimated revenues generated for the budget are obtained from current and historical data.

Summary of Material Incorporated by Reference

The “Application to Operate a Pharmacy in Kentucky”, June 2023 form is the 11-page form to be utilized by applicants for an initial resident pharmacy permit.

The “Application for “Resident Pharmacy Permit –Renewal”, June 2023 form is the 12-page form to be utilized by applicants for annual resident pharmacy permit renewal.

