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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.

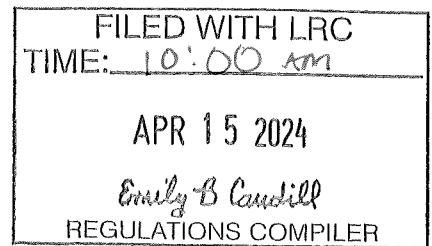
DATE: April 15, 2024

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 2:030. License transfer and Non-Resident Pharmacist License.

5 RELATES TO: KRS 315.191(1)(c), (d), 315.210. KRS 315.050

6 STATUTORY AUTHORITY: KRS 218A.205(8), 315.191(1)(a), (c), (d), 315.210

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.210 authorizes the board to
8 establish conditions for licensure by reciprocity. KRS 218A.205(8) requires the board to
9 establish requirements for background checks for licensees. This administrative
10 regulation establishes conditions, forms, and examination requirements for licensure by
11 reciprocity and for licensure of non-resident pharmacists.

12 Section 1. Definitions.

13 (1) "Board" is defined by KRS 315.010(4).

14 (2) "Good standing" means that a license is not suspended, revoked, surrendered,
15 conditioned under terms of probation, or otherwise in a status that in any manner
16 restricts the activity of the licensee.

17 (3) "License transfer" means a license to practice pharmacy in Kentucky issued by the
18 board to a pharmacist licensed in another jurisdiction.

19 (4) [(3)] "NABP" means the National Association of Boards of Pharmacy.

1 (5) "Non-Resident Pharmacist License" means a license issued by the Board to a
2 pharmacist licensed and located in another jurisdiction to practice pharmacy to citizens
3 in Kentucky.

4 Section 2. An applicant licensed in another jurisdiction shall be eligible for license
5 transfer, if the:

6 (1) Requirements for licensure of the jurisdiction that granted his or her license met or
7 exceeded Kentucky requirements for licensure when the license in the other jurisdiction
8 was granted;

9 (2) Applicant holds in good standing, an active license to practice pharmacy;

10 (3) Applicant has:

11 (a) Completed and certified the NABP Preliminary Application for Transfer of
12 Pharmacist License form; and

13 (b) Received an NABP Official Application for Transfer of Pharmacist License;

14 (4) Applicant is currently in good standing in the jurisdiction from which he or she has
15 applied;

16 (5) Applicant has successfully completed an examination in jurisprudence;

17 (6) Applicant has submitted to a nation-wide criminal background investigation by
18 means of fingerprint check by the Department of Kentucky State Police and the Federal
19 Bureau of Investigation; and

20 (7) Applicant has submitted to a query to the National Practitioner Data Bank of the
21 United States Department of Health and Human Services.

22 Section 3.

1 Required Information. An applicant shall provide the information required by the NABP
2 Preliminary Application for Transfer of Pharmacist License form, including:
3 (1) Name, maiden, and other names used currently or previously;
4 (2) Address, telephone number;
5 (3) Date of birth;
6 (4) Social Security number;
7 (5) Citizenship;
8 (6) Sex;
9 (7) State of original license by examination, including:
10 (a) License number;
11 (b) Original date of issue;
12 (c) Current status of original licensure; and
13 (d) State for which license transfer is requested;
14 (8) Pharmacy education, including:
15 (a) Name and location of pharmacy school;
16 (b) Name of pharmacy degree;
17 (c) Date degree was received; and
18 (d) Other professional degrees, including the information specified by paragraphs (a) to
19 (c) of this subsection;
20 (9) Whether the applicant has earned certification by the Foreign Pharmacy Graduate
21 Examination Committee, and, if so, the examination equivalency number assigned;
22 (10) Total hours of practical experience as an intern prior to licensure as a pharmacist;
23 (11) States, dates, and results of pharmacist licensure examinations;

- 1 (12) Pharmacist licenses currently held, including issue date, expiration date, status,
2 and any board action taken against the licensee;
- 3 (13) Practice and employment, including nonpharmacist employment, from the past
4 three (3) years;
- 5 (14) Record of charges or convictions of any felony or misdemeanor offense, other than
6 traffic offenses, and whether or not a sentence was imposed or suspended;
- 7 (15) Record of any surrender of a pharmacist license or registration issued by the
8 federal government or any state controlled substance authority;
- 9 (16) Record of any pharmacist license revocation, suspension, restriction, termination,
10 or other disciplinary action by any board of pharmacy or other state authority;
- 11 (17) Record of whether the pharmacist is currently under investigation or subject to
12 disciplinary action by the licensing jurisdiction, federal Food and Drug Administration,
13 federal Drug Enforcement Administration or any state drug enforcement authority for the
14 violation of any state or federal pharmacy, liquor, or drug laws;
- 15 (18) Record of any condition or impairment, such as substance or alcohol abuse or
16 dependency that in any way affects the pharmacist's ability to practice pharmacy in a
17 safe and competent manner; and
- 18 (19) Record of any application for initial licensure, renewal licensure, or licensure by
19 transfer that was denied by any licensing authority, whether in pharmacy or any other
20 profession.

21 Section 4.

22 The board shall accept license transfer applications from jurisdictions that:

- 23 (1) Are an active member of the NABP; and

1 (2) Grant license transfers to pharmacists pursuant to conditions and requirements that
2 are the equivalent of conditions and requirements established by the board.

3 Section 5. An applicant for license transfer shall take and pass the Multistate Pharmacy
4 Jurisprudence Examination administered by the NABP and shall pay the fees in 201
5 KAR 2:050(1) and (19).

6 Section 6. An applicant licensed in another jurisdiction shall be eligible for non-resident
7 pharmacist license if the applicant:

8 (1) Holds in good standing an active license to practice pharmacy in any state;

9 (2) The applicant is issued a NABP Verify credential; and

10 (3) The applicant submits to a fingerprint-supported criminal record check by the
11 Department of Kentucky State Police and the Federal Bureau of Investigation pursuant
12 to KRS 218A.205(8).

13 Section 7. An applicant for non-resident pharmacist license shall be exempt from:

14 (1) The requirements for license transfer;

15 (2) The Multistate Pharmacy Jurisprudence Examination administered by NABP; and

16 (3) Continuing Education requirements of Kentucky.

17 Section 8. A non-resident pharmacist licensee shall:

18 (1) Maintain participation in the NABP Verify Program;

19 (2) Submit an initial application for non-resident pharmacist licensure;

20 (3) Submit an annual renewal of non-resident pharmacist license; and

21 (4) Pay the annual renewal of a pharmacist non-resident license fee established in 201
22 KAR 2:050.

1 Section 9. The following acts are prohibited with the utilization of a non-resident
2 pharmacist license:

3 (1) Engaging in the practice of pharmacy in Kentucky while:

4 (a) Residing in Kentucky; or

5 (b) Employed by a pharmacy located in Kentucky; and

6 (2) Serving as a pharmacist-in-charge of a Kentucky permitted facility.

7 [~~Section 6 Fee. An applicant shall include the fees specified by 201 KAR 2:050, Section~~
8 ~~4(2) and (19).~~]

9 Section 10. [Section 7.] Board Discretion.

10 (1) The Board maintains the discretion to deny an applicant a licensee if the applicant
11 fails to demonstrate good mental health and moral character pursuant to KRS
12 315.050(1);

13 (2) The board may waive the provisions of section 9 of this administrative regulation
14 during a declared state of emergency.

15 Section 12. Incorporation by Reference (1) The following material is incorporated by
16 reference:

17 (a) "NABP Preliminary Application for Transfer of Pharmacist License", April 2018[~~is~~
18 incorporated by reference].

19 (b) "Application/Renewal for Non-Resident Pharmacist License", 04/2024.

20 (2) This material may be inspected, copied, or obtained, subject to applicable copyright
21 law at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125
22 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
23 or on the Web site at <https://pharmacy.ky.gov/professionals/Pages/Pharmacists.aspx>

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April 15, 2024

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

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 2:030. License transfer and Non-Resident Pharmacist License

Contact person: Christopher 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 conditions, forms, and examination requirements for licensure by reciprocity and for licensure of non-resident pharmacists.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to inform pharmacists of the conditions, forms, and examination requirements for reciprocal licensure and non-resident licensure.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation, authorized by KRS 315.191 (1)(a), establishes conditions, forms, and examination requirements for licensure by reciprocity and for licensure of non-resident pharmacists. This administrative regulation conforms to the authorizing statute because the authorizing statute gives the board authority to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will ensure that pharmacists are informed of the conditions, forms, and examination requirements for reciprocal licensure and non-resident 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: This amendment to an existing administrative regulation establishes a new classification of pharmacist licensure. This amendment to an existing administrative regulation establishes conditions, forms, and examination requirements for licensure of non-resident pharmacists.

(b) The necessity of the amendment to this administrative regulation: This amendment to an existing administrative regulation is necessary to inform non-resident pharmacists of the conditions, forms, and examination requirements for non-resident licensure.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment to an existing administrative regulation, authorized by KRS 315.191 (1)(a), establishes conditions, forms, and examination requirements for non-resident licensure. This amendment to an existing administrative regulation conforms to the authorizing statute because KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(d) How the amendment will assist in the effective administration of the statutes: This amendment provides rules for non-resident pharmacist licensure.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates that pharmacists seeking reciprocity and non-resident pharmacists will be affected, as pharmacists seeking reciprocity and non-resident pharmacists will need to comply with

this administrative regulation to obtain licensure. 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 to be 9,250 pharmacists.

(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: 1. Pharmacists seeking reciprocity and non-resident pharmacists will have to familiarize themselves with this administrative regulation. 2. This administrative regulation establishes conditions, forms, and examination requirements for licensure by reciprocity and for licensure of non-resident pharmacists. 3. The board will help educate identified entities of this amendment to an existing administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Reciprocal applications cost \$250, and this is not being amended. Applications for non-resident licensure will cost \$50. These fees are in 201 KAR 2:050.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): These pharmacists will have the benefit of practicing pharmacy in Kentucky.

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

(a) Initially The Kentucky Board of Pharmacy is implementing a new licensing management software in 2024. The cost associated with this new software included the anticipated changes with the proposed and amended regulations. The base price for the software is \$220,500 plus the implementation cost of \$88,200. The yearly 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 cost 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. :

(b) On a continuing basis: 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.

(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: An amendment to 201 KAR 2:050 includes a new fee for non-resident licensure that has been created here.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This regulation does not establish any fees, but in the non-resident licensure application, a fee is referenced. This fee originates in 201 KAR 2:050.

(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 seeking license transfer and all out of state pharmacists seeking a nonresident license.

FISCAL IMPACT STATEMENT

201 KAR 2:030. License transfer and Non-Resident Pharmacist License
Contact person: Christopher Harlow, Phone 502-564-7910, 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) authorizes the Board to regulate pharmacists through licensing.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions: The promulgating agency, the Board of Pharmacy, is the only affected state unit impacted.

(a) Estimate the following for the first year:

Expenditures: The board is implementing new licensing management software in 2024. The cost associated with this software includes the anticipated changes from this amendment. The base price for the software is \$220,500 plus the implementation cost of \$88,200. The yearly support and maintenance is \$66,150. Additional administrative costs include personnel costs for licensing pharmacists. The Board estimates the annual personnel cost to be approximately \$132,000.

Revenues: The Board estimates additional revenues to be approximately \$462,500 from annual renewals from non-resident pharmacists and those that practice into Kentucky via license transfer.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? It will depend on the number of applicants seeking transfer or to become a non-resident pharmacist licensee.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): There are no local affected entities with the exception of the Board.

(a) Estimate the following for the first year:

Expenditures: n/a

Revenues: n/a

Cost Savings: n/a

(b) How will expenditures, revenues, or cost savings differ in subsequent years? n/a

(4) Identify additional regulated entities not listed in questions (2) or (3): Out of state pharmacists are the regulated party that will be impacted by this regulation. This includes those applicants seeking license transfer and those pharmacists seeking a non-resident pharmacist license.

(a) Estimate the following for the first year:

Expenditures: \$50 for a non-resident pharmacist license and \$50 for the annual renewal. For transfer/reciprocating pharmacists, the cost is \$250 initially and \$105 each year for renewal.

Revenues: n/a

Cost Savings: n/a

(b) How will expenditures, revenues, or cost savings differ in subsequent years? It will depend on the number of pharmacists seeking license transfer or a non-resident pharmacist license.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: The fiscal impact rests on pharmacists that are seeking licensure in Kentucky via the license transfer route or the limited license that can be obtained via non-resident pharmacist licensure. For transfer applicants, the cost is \$250 with an annual renewal of \$105. For non-resident pharmacist license applicants, the cost is \$50 and the renewal cost is \$50. If pharmacies pay for their pharmacists non-resident in aggregate, these numbers could be increased for the initial licensing of non-resident pharmacists. Currently 47.6% of pharmacists licensed with the Board are located outside of Kentucky.

(b) Methodology and resources used to determine the fiscal impact: The estimated revenues generated for the budget are obtained from current and historical data.

(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.

(b) The methodology and resources used to reach this conclusion: Agency data including the number of pharmacists that might seek a non-resident pharmacist license, as collected from pharmacy responses.

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

The "NABP Preliminary Application for Transfer of Pharmacist License", Form April 2018, is the National Association of Boards of Pharmacy form that pharmacists utilize when applying for license transfer to the Kentucky Board of Pharmacy.

"Application/Renewal for Non-Resident Pharmacist License" Form 04/2024 is the application all out of state pharmacists must use when applying for a non-resident pharmacist license.

SUMMARY OF CHANGES TO MATERIAL INCORPORATED BY REFERENCE

The application/renewal for non-resident pharmacist licensure is new.

There have been no changes to the NABP Preliminary Application for Transfer of Pharmacist License.