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Representative Derek Lewis
Legislative Research Commission
083, Capital Annex
702 Capitol Avenue
Frankfort, Kentucky 40601

December 2, 2024

Dear Co-Chairs,

After consideration of the issues raised by 201 KAR 2:050 and the attorney general's opinion referencing such, the Board of Pharmacy proposes the attached agency amendment to this ordinary administrative regulation.

Sincerely,

Christopher Harlow, Executive Director
Kentucky Board of Pharmacy

Final, 11-22-2024

AGENCY AMENDMENT

BOARDS AND COMMISSIONS

Board of Pharmacy

201 KAR 2:050. Licenses and permits; fees.

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Section 1(18)

Line 11

After "\$150;", insert "and".

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Section 1(19) through 1(22)

Lines 13-16

After "(25) dollars", delete the following:

- ;
- (20) Application for non-resident pharmacist license - fifty (50) dollars;
 - (21) Renewal for non-resident pharmacist license - fifty (50) dollars; and
 - (22) Delinquent renewal penalty for non-resident pharmacist license - fifty (50) dollars

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

At the time the agency files this agency amendment, the agency shall file one (1) clean updated copy of its RIA that:

- Includes updated answers to Questions (2)(a), (b) and (d), (3), (4)(a) and (b), 5(b), (7), and (8) for consistency and to delete references to the additional fees for non-resident pharmacists and the licensure of non-resident pharmacists that have been removed from the regulation.

FISCAL IMPACT STATEMENT

At the time the agency files this agency amendment, the agency shall file one (1) clean updated copy of its Fiscal Impact Statement that:

- Includes an updated answer to Question (5)(b) for consistency with the changes of removing the non-resident pharmacist license from the regulation.

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.

(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.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: 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: The amendments simply move the location of the material incorporated by reference and provide that all fees are non-refundable and that applications expire after one year.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The fee is different depending on what type of licensee or permit holder the party is. No fees are being amended by this regulation.

(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.

(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: No new fees are necessary to implement this amendment.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This amendment does not establish or directly or indirectly increase any fees. This is a fee regulation that does contain the licensing fees for license and permit holders.

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

(2) Identify the promulgating agency and any other affected state units, parts, or divisions: The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(a) Estimate the following for the first year:

Expenditures: 3,268,700

Revenues: 2,730,000

Cost Savings: none

(b) How will expenditures, revenues, or cost savings differ in subsequent years? In subsequent years, the expenditures are projected to be \$3,328,800 and the revenues approximately \$3,312,500.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): There are no local entities affected by this regulation.

(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? There are no local entities impacted by this regulation.

(4) Identify additional regulated entities not listed in questions (2) or (3): Regulated entities include all pharmacies, wholesalers, resident manufacturers, pharmacists, and interns.

(a) Estimate the following for the first year:

Expenditures: It is dependent upon the type of regulated entity.

Revenues: It is dependent upon the type of regulated entity.

Cost Savings: It is dependent upon the type of regulated entity.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? The expenditures should remain the same.

(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.

(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). In total, because permit and licensing fees are how the Board funds its operations, this administrative 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.