

PUBLIC PROTECTION CABINET
Department of Insurance
Division of Health, Life, Managed Care
(Amendment)

806 KAR 9:360. Pharmacy Benefit Manager License.

RELATES TO: KRS 14A.4-010, 304.1-050, 304.2-290, 304.2-310, 304.9-020, 304.9-053, 304.9-054, 304.9-055, 304.9-133, 304.10-030, 304.10-040, 304.17A-005, 304.17A-162, 304.17A-163, 304.17A-165, ~~304.17A-440~~, 304.17A-535, 304.17A-607, 304.17A-617-304.17A-633, 304.99-020, 45 C.F.R. 156.122

STATUTORY AUTHORITY: KRS 304.2-110(1), 304.9-053(2), 304.9-054(3)~~(6)~~, 304.9-054(4), 304.9-055

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes the commissioner ~~of Insurance~~ to promulgate reasonable administrative regulations necessary for or as an aid to the effectuation of ~~any provision of~~ the Kentucky Insurance Code as defined in 304.1-010. KRS 304.9-053(2) requires a pharmacy benefit manager seeking a license to apply to the commissioner in writing on a form provided by the department. KRS 304.9-054(3)~~(6)~~ requires the department to promulgate administrative regulations to implement and enforce the provisions of KRS 304.9-053, 304.9-054, 304.9-055, and 304.17A-162. 304.9-054(4) permits the department to impose a fee upon pharmacy benefit managers, in addition to a license fee, to cover the costs of implementation and enforcement of 205.647 and any provision of KRS Chapter 304 applicable to pharmacy benefit managers, including but not limited to this section and 304.9-053, 304.9-055, and 304.17A-162. This administrative regulation establishes requirements for the licensure of pharmacy benefit managers.

Section 1. Definitions.

- (1) "Admitted insurer" is defined by KRS 304.10-030(1).
- (2) "Commissioner" is defined by KRS 304.1-050(1).
- (3) "Department" is defined by KRS 304.1-050(2).
- (4) "Nonadmitted insurer" is defined by KRS 304.10-030(8).
- (5) "Pharmacy benefit manager" is defined by KRS 304.9-020(15).

Section 2. Initial License and Renewal.

(1) An applicant for a pharmacy benefit manager license or renewal license from the commissioner shall submit the following to the department in the format as outlined in the instructions on the Pharmacy Benefit Manager License Application:

- (a) Form PBM, The Pharmacy Benefit Manager License Application;
- (b) The fee set forth in KRS 304.9-053(3) and the penalty fee, if applicable, set forth in KRS 304.9-053(4)~~(5)~~;
- (c) The following evidence of financial responsibility:

1. A certificate of insurance from either an admitted insurer or a nonadmitted insurer, in accordance with KRS 304.10-040, stating that the insurer has and will keep in effect on behalf of the pharmacy benefit manager a policy of insurance covering the legal liability of the licensed pharmacy benefit manager's erroneous acts or failure to act in its capacity as a pharmacy benefit manager, and payable to the benefit of any aggrieved party in the sum of not less than \$1,000,000; or
2. A cash surety bond issued by a corporate surety authorized to issue surety bonds in this commonwealth, in the sum of \$1,000,000, which shall be subject to lawful levy of execution by any party to whom the licensee has been found to be legally liable;

(d) The name of at least one (1) responsible individual who shall be responsible for the pharmacy benefit manager's compliance with KRS Chapter 304 and KAR Title 806 and who is:

1. Licensed as an administrator in Kentucky; and
2. Designated in accordance with KRS 304.9-133;

(e) If performing utilization review in accordance with KRS 304.17A-607, the pharmacy benefit manager's utilization review registration number;

(f) The following written policies and procedures to be used by the pharmacy benefit manager:

1. An appeals process for any pricing system used to determine the cost of a generic drug required by KRS 304.17A-162;
2. Exceptions policy required by 45 C.F.R. 156.122(c) and KRS 304.17A-535(4); and
3. Pharmacy and Therapeutics committee membership standards and duties required by 45 C.F.R. 156.122(a);

(g) Proof of a registered agent and office with the Kentucky Secretary of State in accordance with KRS 14A.4-010;

(h) Provide a listing of all clients PBM provides services to including any non-ERISA self-funded or governmental plans; and

(i) Provide a listing of any delegated or contracted companies that perform part of the PBM services.

(2)

(a) Upon receipt of a complete application as required by subsection (1) of this section, the commissioner shall review the application and:

1.
 - a. Approve the application; and
 - b. Issue the applicant the pharmacy benefit manager license;
2. Notify the applicant that additional information is needed in accordance with paragraph (b) of this subsection; or
3. Deny the application in accordance with paragraph (c) of this subsection.

(b)

1. If supplemental or additional information is necessary to complete the application, the applicant shall submit that information within thirty (30) days from the date of the notification from the commissioner.

2. If the missing or necessary information is not received within thirty (30) days from the date of the notification, the commissioner shall deny the application unless good cause is shown. To determine if the applicant has demonstrated good cause, the commissioner shall weigh the justification provided against any other issues, including if the applicant had submitted any prior good cause excuses for the same request. Some examples of good cause include:

- a. Personnel-related issues, including the individual responsible for responding was transferred, terminated, or became incapacitated due to illness;
- b. A need to obtain information that was not immediately available and had to be requested from other sources;
- c. A lack of sufficient resources to respond to large requests; and
- d. Information technology, operational, or equipment malfunctions causing unexpected delays.

(c) If the commissioner determines that the applicant does not meet the requirements for licensure, or if the application is denied pursuant to paragraph (b)2. of this subsection, the commissioner shall:

1. Provide written notice to the applicant that the application has been denied; and

2. Advise the applicant that a request for a hearing may be filed in accordance with KRS 304.2-310.

(3)

(a) ~~A [Except as provided in paragraph (b) of this subsection, a] pharmacy benefit manager license shall:~~

1. Be renewed annually as required by subsection (4) of this section; or
2. Expire on March 31.

(b) An applicant for a pharmacy benefit manager license shall pay a registration fee of \$10,000 and a license application fee of \$1,000 within thirty (30) days of initial licensure and annually thereafter on or before March 31. [If the license was issued on or before January 1, 2017, the license shall expire on March 31, 2018, if not renewed as required by subsection (4) of this section.]

(4)

(a) A renewal application shall include the items required by subsection (1) of this section.

(b) If the renewal application is submitted after the renewal date of March 31 but between April 1 and May 31, the application required by subsection (1) of this section shall be accompanied by a penalty fee of \$500 in accordance with KRS 304.9-053(4~~5~~). A license approved by May 31 shall be considered continuously active.

Section 3. Notice of Changes. Within thirty (30) days of any change, a licensee shall notify the commissioner of all changes among its members, directors, officers, and other individuals designated or registered to the license, any changes to the listing of clients and delegated contractors provided in the most recent application filed by the licensee, and any changes to its written policies and procedures submitted pursuant to Section 2(1)(f) of this administrative regulation.

Section 4. Incorporation by Reference.

(1) "Pharmacy Benefit Manager License Application", Form PBM, 10/~~2024~~~~[2024]~~, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, Mayo-Underwood Building, 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the Web site at: <http://insurance.ky.gov/ppc/CHAPTER.aspx>.

SHARON P. CLARK, Commissioner
RAY A. PERRY, Secretary

APPROVED BY AGENCY: November 14, 2024

FILED WITH LRC: November 14, 2024 at 2:35 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 AM on January 23, 2025, at 500 Mero Street, Frankfort, KY 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. If held, this hearing will be 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 11:59 PM on January 31, 2025. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: Shaun T. Orme, Executive Advisor, 500 Mero Street, Frankfort, KY 40601, Phone: (502) 782-1698, Fax: (502) 564-1453, Email: shaun.orme@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Shaun T. Orme

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes an annual registration fee for pharmacy benefit managers, pursuant to 2024 Regular Session Senate Bill 188.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to provide the additional funds to support the new requirements of 2024 Regular Session Senate Bill 188.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 304.9-054(7) says that we can impose a fee, in addition to license fee, to cover the costs of implementation of KRS 304.9-054. 2024 Regular Session Senate Bill 188 requires the regulation to provide for additional programs and administrative review that will result in increased expense to the Department, which may be offset by the licensees. This amendment provides the amount required by the new registration fee.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This amendment provides the amount required by the new registration fee.

(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 establishes an annual registration fee.

(b) The necessity of the amendment to this administrative regulation:

This amendment is required to offset the expenses resulting from the implementation of 2024 Regular Session Senate Bill 188.

(c) How the amendment conforms to the content of the authorizing statutes:

2024 Regular Session Senate Bill 188 requires the regulation to provide for additional programs and administrative review that will result in increased expense to the Department, which may be offset by the licensees.

(d) How the amendment will assist in the effective administration of the statutes:

This amendment provides the amount required by the new registration fee.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

Over 50 pharmacy benefit management entities will be impacted by this administrative 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:

The pharmacy benefit management entities will have to pay the annual registration fee upon issuance of a license and annually thereafter.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

This amendment will cost the pharmacy benefit management entities ten thousand dollars (\$10,000), annually.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Pharmacy benefit management entities will be able to pay a uniform fee to share in the cost of the increased burden placed on the industry to protect consumers from unregulated practices.

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

(a) Initially:

Approximately six hundred sixty thousand dollars (\$660,000).

(b) On a continuing basis:

Approximately six hundred sixty thousand dollars (\$660,000).

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

The Department of Insurance's operational budget and the new annual registration fee.

(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:

The purpose of this amendment is to increase fees.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

Yes, this regulation establishes a ten thousand dollar (\$10,000) annual fee.

(9) TIERING: Is tiering applied?

Tiering is not applied as the provisions of this administrative regulation apply to all entities equally.

FISCAL IMPACT STATEMENT

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

KRS 304.2-110(1), 304.9-053(2), 304.9-054(6), and KRS 304.9-055.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Kentucky Department of Insurance as the implementer.

(a) Estimate the following for the first year:

Expenditures:\$660,000

Revenues:\$570,000

Cost Savings:None

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

No difference.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

No local entities affected.

(a) Estimate the following for the first year:

Expenditures:

Revenues:

Cost Savings:

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

No difference.

(4) Identify additional regulated entities not listed in questions (2) or (3):

Pharmacy Benefit Managers (PBMs) that apply for a PBM license or renew a PBM license.

(a) Estimate the following for the first year:

Expenditures:\$10,000 per PBM

Revenues:None

Cost Savings:None

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

No difference. Expenditures will be \$10,000 per year.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

This administrative regulation will increase fees paid by PBMs to obtain and renew a PBM license. An additional \$10,000 registration fee is required of PBMs, in addition to the current li-ense fee of \$1,000. There are currently 57 licensed PBMs in Kentucky. This will result in an overall revenue increase for the Department of \$570,000.

(b) Methodology and resources used to determine the fiscal impact:

(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)

Yes, this administrative regulation will have a major economic impact.

(b) The methodology and resources used to reach this conclusion:

Yes, this administrative regulation will have major impact in the aggregate for both the Department and PBMs. SB 188 was enacted during the 2024 legislative session. SB 188 significantly increased the Department's regulatory oversight of PBMs, including requiring the Department to conduct a study, at least every two years, to determine the average dispensing fee for pharmacies in Kentucky. To properly conduct the study, the Department will need to contract with a firm that has experience conducting similar studies. The estimated cost for performing this work, along with hiring additional staff, is \$660,000. This estimate is based on similar contract work performed for the Department by contract actuaries and the cost of adding the necessary additional staff. PBMs currently pay a \$1,000 application fee to obtain or renew a PBM license. The regulation proposes to impose an additional \$10,000 registration fee for each PBM that requests a PBM license or renews a PBM license. There are currently 57 licensed PBMs in Kentucky. Therefore, the overall cost imposed on the PBMs will be \$570,000.