

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-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), 304.9-054(4), 304.9-055

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes the commissioner to promulgate reasonable administrative regulations necessary for or as an aid to the effectuation 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) 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);
- (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 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.

(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). 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, 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.