

Pharmacy Benefits Manager Licensure Act; Maximum Allowable Cost Pricing and Appeals; House Sub. for SB 28

House Sub. for SB 28 enacts law and amends requirements requiring registration of pharmacy benefits managers (PBMs) with the Commissioner of Insurance (Commissioner) to instead require licensure under the Pharmacy Benefits Manager Licensure Act (PBM Licensure Act). The bill establishes new licensure, administrative, and enforcement requirements on PBMs; maintains regulation under Chapter 40, Article 38 of the *Kansas Statutes Annotated*; and adds a new section to the PBM Licensure Act. The bill also amends provisions pertaining to maximum allowable cost (MAC) pricing and the appeals process.

On and after January 1, 2023, a person could not perform, act, or do business in Kansas as a PBM unless the person has a valid license issued by the Commissioner pursuant to the PBM Licensure Act.

PBM Licensure Act (New Section 1, Sections 2-8)

Disciplinary Action (New Section 1)

The bill will allow a PBM's license to be revoked, suspended, or limited, or the licensee to be censured or placed under probationary conditions, or an application for a license or reinstatement to be denied, upon a finding of the existence of any of the following grounds:

- The applicant or licensee committed fraud or misrepresentation in applying for or securing an original, renewal, or reinstated license;
- The licensee has violated any lawful rule and regulation promulgated by the Commissioner or violated any lawful order or directive of the Commissioner previously entered by the Commissioner;
- The PBM has engaged in a fraudulent activity that constitutes a violation of state or federal law;
- The licensee has failed to furnish to the Commissioner, or the Commissioner's investigators or representatives, any information legally requested by the Commissioner;
- The PBM has been determined by the Commissioner to be in violation of or in noncompliance with state or federal law; or
- The PBM has failed to timely submit a renewal application and the information required under KSA 40-3824. In lieu of a denial of a renewal application, the Commissioner could permit the PBM to submit to the Commissioner a corrective action plan to correct or cure any deficiencies.

PBM Licensure Act – Act Designation (Section 2)

The bill renames KSA 40-3821 through KSA 40-3828 from the Pharmacy Benefits Registration Act to the Pharmacy Benefits Manager Licensure Act, adds section 1 of the bill to the PBM Licensure Act, and requires, on and after January 1, 2023, any PBM performing, acting, or doing business in Kansas to hold a valid license issued by the Commissioner pursuant to this act.

The bill also amends law, previously applying to the registration of PBMs (licensed under provisions of this bill), to state a license issued in accordance with this act is nontransferrable.

PBM Licensure Act – Definitions (Section 3)

The bill amends definitions associated with the regulation of PBMs to add definitions for the terms “act,” “department,” “ERISA,” “health benefit plan,” “health insurer,” and “maximum allowable cost or MAC.” “Department” is defined to mean the Insurance Department (Department).

PBM Licensure Act – Application; Application Fee; Information Deemed Confidential and Privileged (Section 4)

Application form. The bill updates law requiring registration with the Commissioner to reflect licensure and requires this new information to be included on the application form:

- Name, address, and telephone number of the PBM;
- Name, address, phone number, email address, and official position of the employee who will serve as the primary contact for the Department;
- A copy of the PBM’s corporate charter, articles of incorporation, or other charter document;
- A template contract, which the bill requires to include a dispute resolution process, that ultimately involves an independent fact finder between:
 - The PBM and the health insurer; or
 - The PBM and the pharmacy or a pharmacy’s contracting agent; and
- A network adequacy report on a form prescribed by the Department through rules and regulations.

The bill also modifies language in a continuing requirement to provide information pertaining to the name, address, official position, and professional qualifications of individuals responsible for the conduct of the affairs of the PBM to remove from the list of individuals any other person who exercises control or influence over the affairs of the PBM.

Application fee. The bill increases the nonrefundable application fee from \$140 (registration) to \$2,500 (licensure).

Material change of application information; review of application by Commissioner. The bill requires the licensee to inform the Commissioner of any material change to the application form and related submitted information within 90 days of such change. Failure to timely inform the Commissioner of a material change could result in a penalty in the amount of \$500. The bill also requires, within 90 days of receipt of a completed application, the network adequacy report, and the applicable license fee, the Commissioner to review the application and issue a license if the applicant is deemed qualified. If the Commissioner determines the applicant is not qualified, the Commissioner is required to notify the applicant and specify the reason for denial.

Confidential and privileged information. The bill provides that all documents, materials, or other information and copies in the possession or control of the Department or any other governmental entity that are obtained by or disclosed to the Commissioner or any other person in the course of an application, examination, or investigation made pursuant to this act shall be confidential by law and privileged; shall not be subject to any open records, freedom of information, sunshine, or other public record disclosure laws; and shall not be subject to subpoena or discovery. The bill further specifies that the confidentiality provisions apply only to the disclosure of confidential documents outlined in the bill (e.g., information disclosed in the course of an application, examination, or investigation) by the Department or other governmental entity and these provisions should not be construed to create any privilege in favor of any other party. The provision pertaining to confidentiality and disclosure will expire on July 1, 2027, unless the Legislature reviews and reenacts this provision pursuant to KSA 45-229 (Kansas Open Records Act, legislative review of exceptions to disclosure) prior to July 1, 2027.

PBM Licensure Act – Licensure Expiration and Renewal; Fees (Section 5)

The bill maintains the current (registration) expiration date of March 31 each year, providing a PBM license would expire on March 31 and permitting annual renewal at the request of the licensee. The bill increases the renewal fee from \$140 (registration) to \$2,500 (licensure), increases the penalty fee for failure to pay the renewal fee by the prescribed date from \$140 (registration) to \$2,500 (licensure), and requires any person performing pharmacy benefits management service to obtain a license as a PBM no later than January 1, 2023, in order to continue to do business in Kansas.

PBM Licensure Act – Rules and Regulations (Section 6)

The bill requires the Commissioner to adopt, amend, and revoke all necessary rules and regulations no later than July 1, 2023.

PBM Licensure Act – Violations of the PBM Licensure Act; Appeals Hearing; Penalties and Fines (Section 7)

The bill authorizes the Commissioner, if the Commissioner has reason to believe that a PBM has been engaged in this state or is engaging in this state in activity that violates the PBM Licensure Act, to issue and serve on a PBM a statement detailing the charges of violation and to conduct a hearing in accordance with the provisions of the Kansas Administrative Procedure Act.

If, after a hearing, the Commissioner determines that the PBM subject to the charges has violated the PBM Licensure Act, the Commissioner would be permitted to, in the exercise of discretion, order any one or more of the following:

- Payment of a monetary penalty of not more than \$1,000 for each and every act or violation. The bill specifies the total of the monetary penalties for such violations cannot exceed \$10,000;
 - If the PBM knew or reasonably should have known that such manager was in violation of this act, payment of a monetary penalty of \$5,000 for each and every act or violation. The total of the monetary penalties for these violations could not exceed \$50,000 in any six-month period;
- If the PBM knew or reasonably should have known such person was in violation of this act, the suspension or revocation of the PBM's license; or
- The assessment of any costs incurred as a result of conducting the administrative hearing authorized by provisions of this bill against the PBM. The bill defines "costs," as used in this section, to include witness fees, mileage allowances, any costs associated with reproduction of documents that become part of the hearing record, and expenses of making a record of the hearing.

The bill further provides that if the deadline for filing a petition for review has expired and no petition has been filed, the Commissioner may reopen and modify or set aside any portion or the entirety of any administrative order issued under provisions of the bill. The bill also specifies that the reopening of any such order may occur if, in the Commissioner's opinion, the conditions of fact or law have changed to warrant such action or if such an action is warranted in the public interest.

The bill also modifies the fine associated with failure to register with the Commissioner (\$500) to a fine associated with failure to be licensed and sets this fine at \$5,000 for the period of time the PBM is found to be in violation.

PBM Licensure Act – Licensure Fund (Section 8)

The bill renames the PBM Registration Fund as the Pharmacy Benefits Manager Licensure Fund (Fund) and establishes the Fund in the State Treasury, requires administration by the Commissioner for costs associated with licensing, and provides for expenditures from this Fund. All moneys deposited in the Fund will continue to be credited to the Fund.

PBM – Maximum Allowable Cost (Sections 9-10)

MAC Pricing and Definitions (Section 9)

The bill amends law relating to MAC pricing and reimbursements to pharmacies. The bill updates the definition of "maximum allowable cost or MAC" to assign the definition established in the PBM Licensure Act. The bill also creates these definitions:

- “Pharmacy benefits plan or pharmacy benefits program” means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in this state; and
- “Wholesaler” means a person or entity that sells and distributes prescription pharmaceutical products, including, but not limited to, a full line of brand name, generic, and over-the-counter pharmaceuticals and that offers regular and private delivery to a pharmacy.

MAC List Requirements; Updates; Appeals Process (Section 10)

The bill amends law pertaining to the MAC list and reimbursement appeals process for network pharmacies to require the establishment of a reasonable administrative appeal procedure to allow a pharmacy or pharmacy’s contracting agent to challenge MAC for a specific drug as:

- Not meeting requirements of the bill’s provisions pertaining to MAC list; and
- Being below the cost at which the pharmacy may obtain the drug.

The bill requires the following to be included in any administrative appeals procedure:

- A dedicated telephone number and email address or website for the purpose of submitting administrative appeals; and
- The ability to submit an administrative appeal directly to the PBM regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization.

The bill clarifies a continuing provision pertaining to filing of an administrative appeal by a network pharmacy not later than 10 business days after the fill date to authorize the network pharmacy’s contracting agent as well as a network pharmacy to file such an appeal.

The bill also requires the PBM request only the following information to determine a MAC administrative appeal:

- Prescription number;
- Provider’s name;
- National Drug Code (NDC) used during the filing of the claim;
- Date of the fill;
- Reimbursement amount; and
- Such other information related to the appealed claim as required by contract.

The bill also updates provisions pertaining to the denial of the appeal to require the PBM to provide, in addition to the NDC number from a national or regional wholesaler operating in

Kansas meeting certain criteria, the reason for the denial. Provisions in this section (MAC list and appeals process) will apply to PBMs, which include the PBM for the State Health Care Benefits Program (the State Employee Health Plan).