TITLE 365. INSURANCE DEPARTMENT
CHAPTER 25. OTHER LICENSEES

SUBCHAPTER 29. PHARMACY BENEFITS MANAGERS

365:25-29-1. Purpose

The purpose of this Subchapter is to:

(1) Set forth the regulations and procedures relating to the licensing and oversight of pharmacy benefits managers under 59 O.S. §§ 357-360, and

(2) Set forth the regulations and procedures relating to the Patient's Right to Pharmacy Choice Act, 36 O.S. §§ 6958-6968.

365:25-29-2. Scope

This Subchapter shall apply to all pharmacy benefits managers, which must be licensed pursuant to 59 O.S. § 358(A), and to all health insurers subject to compliance with 36 O.S. § 6958 et seq.

365:25-29-3. Authority

This Subchapter is promulgated under the authority granted to the Insurance Commissioner in 59 O.S. § 358(B) and 36 O.S. §§ 6958-6968.

365:25-29-4. Definitions

All definitions contained in 59 O.S. §§ 357-360 and 36 O.S. §§ 6958-6968 are applicable to this Subchapter and in addition:

(1) "**Day**" means a calendar day, unless otherwise defined or limited.

(2) The "**act**" means 59 O.S. §§ 357-360 and 36 O.S. §§ 6858-6968.

(3) Pharmacy benefits manager and PBM may be used interchangeably in this Subchapter.

(4) "**Preferred participating pharmacy**" means a pharmacy that is designated as a preferred participating pharmacy in a PBM's retail pharmacy network.

(5) "**Provider**" means an Oklahoma licensed retail pharmacy.

365:25-29-5. Forms and contents of application for PBM license

An application for PBM License shall be on a form provided by the Commissioner and shall include:

(1) The identity of the PBM and any company or organization controlling the operation of the PBM, including the name, business address, and contact person for the PBM and the controlling entity. For purposes of this subsection, "control" or "controlling" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of the PBM, whether through the ownership of voting securities, by contract or otherwise, unless, for an individual, the power is the result of an official position with or corporate office held by the person;

(2) The name and address of the corporate officers and directors, members and managers (if an LLC), or names of all partners (if a partnership) of the applicant PBM;

(3) A license fee in the amount of One Thousand Dollars ($1,000.00);

(4) A "Certificate of Incorporation" or comparable organizational document from the domiciliary state of the PBM;
(5) In the case of a PBM domiciled outside the State of Oklahoma, a certificate that the PBM is in good standing in the state of domicile or organization;
(6) A report of the details of any suspension, sanction, penalty or other disciplinary action relating to the PBM and its officers and directors;
(7) The name and address of the agent of record for services of process in Oklahoma;
(8) The number of total covered individuals or lives served under all of the PBM's contracts or agreements in Oklahoma;
(9) The most recently concluded fiscal year-end financial statements for the PBM and its controlling entity, which statements have been audited by an independent certified public accountant (CPA) under U.S. generally accepted accounting principles (GAAP); and
(10) A certificate signed by an Executive Officer of the PBM attesting to the accuracy of the information contained in the filing.

365:25-29-6. Surety bond

(a) Prior to the issuance of a pharmacy benefits manager license, the PBM applicant shall file with the Commissioner and thereafter keep in effect, as long as the license remains in effect, a surety bond in an amount determined to be sufficient by the Commissioner. The bond shall be in a form acceptable to the Commissioner and for the purpose of securing conformity with the laws and regulations governing pharmacy benefits managers. The bond shall be for the benefit of parties protected by the provisions of 59 O.S. §§ 357-360 and 36 O.S. §§ 6958-6968.
(b) The surety bond must provide that no party may cancel the bond without first giving thirty (30) days written notice to the principal and the Commissioner.
(c) Absent a finding otherwise, a bond, shall be deemed to be sufficient if it meets the following requirements:

(1) For a PBM with not more than five thousand (5,000) annual Oklahoma covered lives, the bond shall have a minimum penal sum of fifty thousand dollars ($50,000.00);
(2) For a PBM with more than five thousand (5,000) but not more than ten thousand (10,000) annual Oklahoma covered lives, the bond shall have a minimum penal sum of one hundred thousand dollars ($100,000.00);
(3) For a PBM with more than ten thousand (10,000) but not more than twenty-five (25,000) annual Oklahoma covered lives, the bond shall have a minimum penal sum of two hundred fifty thousand dollars ($250,000.00);
(4) For a PBM with more than twenty-five thousand (25,000) but not more than fifty thousand (50,000) annual Oklahoma lives covered, the bond shall have a minimum penal sum of five hundred thousand dollars ($500,000.00);
(5) For a PBM with more than fifty thousand (50,000) but not more than one hundred thousand (100,000) annual Oklahoma lives covered, the bond shall have a minimum penal sum of seven hundred fifty thousand dollars ($750,000.00); and
(6) For a PBM with more than one hundred thousand (100,000) annual Oklahoma covered lives, the bond shall have a minimum penal sum of one million dollars ($1,000,000.00).

365:25-29-7. License term, renewals, fees

(a) An application fee shall not be refundable if the application is denied, withdrawn, cancelled, or refused for any reason by either the applicant or the Commissioner.

(b) The PBM license shall continue in force no longer than twelve (12) months from the original month of issuance. Upon filing a PBM license renewal application on a form provided by the Commissioner, a renewal license may be issued by the Commissioner to a PBM licensee which is in compliance with the act, has continuously maintained such license, and has paid a renewal fee of Five Hundred Dollars ($500.00).

(c) If the PBM fails to timely apply for renewal of its license or fails to pay any applicable fees or outstanding fines by the last day of the month in which the license was originally issued, the license shall expire automatically. After expiration, the PBM license may be reinstated for up to one (1) year following the expiration date upon filing a PBM license renewal application on a form provided by the Commissioner and the payment of a reinstatement fee of One Thousand Dollars ($1,000.00). If after the one-year date the license has not been reinstated, the licensee shall be required to apply for a license as a new PBM licensee applicant.

(d) In the event that the Commissioner declines to issue or renew a PBM license, the Commissioner shall notify the applicant or licensee of such declination and advise the applicant or licensee, in writing, of the reason for the declination. The applicant or licensee may make written demand upon the Commissioner within thirty (30) days of the date of notification by the Commissioner, for a hearing before the Commissioner or an independent hearing examiner appointed by the Commissioner to determine the existence of the grounds for the Commissioner's action. The hearing shall be held within a reasonable time period pursuant to the Oklahoma Administrative Procedures Act.

365:25-29-7.1 Retail pharmacy network access -audit

(a) Standards:

(1) Section 6960 of the act defines "member of a retail pharmacy network" as meaning retail pharmacy providers contracted with a PBM on behalf of a payor in which the pharmacy primarily fills and sells prescription medicine via retail storefront location.

(2) The act draws no distinction between regular or specialty drugs, both being prescription medications, therefore, specialty drugs fall within the contemplation of the act.

(3) Pharmacy benefits managers shall not in any manner on any material, including but not limited to mail and ID cards, include the name of any pharmacy, hospital or other providers unless it specifically lists all pharmacies, hospitals and providers.

(b) A PBM's retail pharmacy network access shall be monitored for compliance with this act by those insurers that utilize the services of such PBM. Health insurers are required to maintain retail pharmacy network access in conformity with the requirements set forth in § 6961 of this act.

(c) Every Insurer that utilizes the services of a PBM shall, as part of the annual general compliance audit required by 365:25-29-9, conduct a network adequacy audit. If the audit reveals the percentage of covered individuals is less than one hundred and five percent (105%) above any of the required percentages in 36 O.S. § 6961 the insurer shall conduct semi-annual network adequacy audits until such time that an audit indicates that the percentage of covered individuals is more than five percent 5% above the required percentage.

(d) The audits must be completed within ninety (90) days of the effective date of 36 O.S. § 6958-6968 and annually each year thereafter. The results of the audits shall be reported to the Commissioner within thirty (30) days of the completion of the audit.

365:25-29-8. PBM to file certain financial statements with the Commissioner

(a) Before March 1 of each year, every PBM providing pharmacy benefits management shall submit to the Insurance Commissioner a report of its financial condition verified by the oath of an executive officer. The report shall be prepared using generally accepted accounting principles and consist of a balance sheet, income statement, and statement of cash flows. The report may be supplemented by any additional information required by the Insurance Commissioner.

(b) The Commissioner may extend the time prescribed for filing annual or other reports or exhibits of any kind for good cause shown. However, the Commissioner shall not extend the time for filing annual statements beyond sixty (60) days after the time prescribed by this Section.

365:25-29-9. Contractual requirements

(a) Maximum Allowable Cost.

(1) Contracts between a PBM and a provider shall conform to the following requirements:

A Identify sources of information utilized by the PBM to create and modify the PBM's maximum allowable cost price specific to the pharmacy;

B The PBM shall provide an electronic process, including but not limited to e-mail, for its pharmacy providers to readily access the MAC list specific to that provider. Upon a provider's written request, a PBM shall furnish its MAC list to the provider in paper form or other agreed format;

C If a provider is unable to obtain a drug from a regional or national wholesaler at a price equal to or less than the PBM's multisource drug product reimbursement, the PBM shall provide a reasonable appeals procedure to contest the multisource drug product reimbursement amount;

D A "reasonable appeals procedure" means a process which permits a provider or a provider's representative to contest a multisource drug product reimbursement amount based on the provider's contention that the drug is not generally available for purchase by Oklahoma pharmacies in the state at or below the PBM's multisource drug product reimbursement;

E A provider's appeal shall contain information including but not limited to the date of claim, National Drug Code number, and the identity of the national or regional wholesalers from which the drug was found to be unavailable for purchase by the provider, at or below the PBM's multisource drug product reimbursement;

F Appeals filed under this subsection shall be presented to the PBM within ten (10) business days following the final adjusted payment date. The PBM must respond to a provider within ten (10) business days following the receipt by the PBM of the notice that the provider is contesting the multisource drug product reimbursement amount;

G If a provider's appeal is denied, the PBM shall provide the reason for the denial, including the National Drug Code number and the identity of the national or regional wholesalers from whom the drug was generally available for purchase by

providers in the state at or below the PBM's multisource drug product reimbursement;

H If a provider's appeal is found to be justified, the PBM shall make a change in the multisource drug product reimbursement amount, permit the provider to reverse and re-bill the claim in question, and make the multisource drug product reimbursement amount change applicable prospectively for all similarly contracted Oklahoma providers.

(2) A PBM shall permit the submission of either paper or electronic documentation to perfect an appeal. A PBM shall not require the submission of appeals on an individual claim (non-batch) basis or refuse to accept appeals from a provider's designated representative or require procedures that have the effect of obstructing or delaying the appeal process. All multisource drug product reimbursement appeals shall be properly documented.

(3) Before beginning business, and as contracts are amended thereafter, each PBM shall submit to the Insurance Commissioner a certificate signed by an executive officer of the PBM attesting that the Oklahoma provider contracts utilized by such PBM satisfy the requirements of the act.

(b) The relationship between a PBM and an insurer or other payor is controlled by contract whereby the PBM acts on behalf of the payor to facilitate the delivery of prescription medication benefits provided by such payor. Requirements and limitations contained within the act and applicable to such payors must be understood within this payor – contractor relationship.

(c) The act requires or limits certain conduct in the interaction between the PBM and retail pharmacy network providers. Consequently, the Department hereby requires that every insurer utilizing the services of a pharmacy benefit manager shall be responsible, as follows:

(1) for approving all contractual documents utilized by its contracted PBMs and its retail pharmacy network to ensure compliance with the act;

(2) for conducting an annual audit of transactions and practices utilized by its contracted PBMs and members of its retail pharmacy network to ensure compliance with the act; and

(3) any exceptions found shall be reported to the Department pursuant to the Commissioner's examination authority.

365:25-29-10. Penalty for noncompliance

(a) After notice and opportunity for hearing, and upon determining that the PBM has violated any of the provisions of 59 O.S. §§ 357-360 of the Oklahoma Statutes, or this Subchapter as it relates to 59 O.S. §§ 357-360, or upon finding the existence of grounds to refuse the issuance or renewal of such license, the Commissioner may suspend or revoke a PBM's license or assess a civil penalty of not less than Five Hundred Dollars ($500.00) nor more than Five Thousand Dollars ($5,000.00) for each instance of violation, or both. Each day that a pharmacy benefits manager conducts business in the State of Oklahoma without a license shall be deemed to be an instance of violation. The payment of the penalty may be enforced in the same manner as civil judgments may be enforced.

(b) After notice and opportunity for hearing, and upon determining that the PBM has violated any of the provisions of 36 O.S. §§ 6958-6968 of the Oklahoma Statutes, or this Subchapter as it

relates to 36 O.S. §§ 6958-6968, the Commissioner may suspend or revoke a PBM's license and/or levy fines not to exceed Ten Thousand Dollars ($10,000.00) for each count for which any PBM has violated the provisions of 36 O.S. §§ 6958-6968. The payment of the penalty may be enforced in the same manner as civil judgments may be enforced.

(c) After notice and opportunity for hearing, and upon determining that the health insurer has violated any of the provisions of 36 O.S. §§ 6958-6968 of the Oklahoma Statutes, the Commissioner may suspend or revoke a health insurer's certificate of authority license or assess a civil penalty of not less than Five Hundred Dollars ($500.00) nor more than Five Thousand Dollars ($5,000.00) for each instance of violation, or both. The payment of the penalty may be enforced in the same manner as civil judgments may be enforced.

(d) Every health insurer upon receipt of any inquiry from the Commissioner or the Commissioner's representative shall, within thirty (30) days from the date of inquiry, furnish the Commissioner or the Commissioner's representative with an adequate response to the inquiry.

365:25-29-11. "Doing pharmacy benefits management business in this state" defined—venue—exceptions

(a) The venue of any act listed in this Section shall be Oklahoma County.

(b) Any one of the following acts, in this state, effected by mail or otherwise, is defined to be doing pharmacy benefits management business in this state:

(1) The making of or proposing to make, as a PBM, a contract with a covered entity for the provision of pharmacy benefits management services to covered individuals residing in Oklahoma;

(2) The provision of pharmacy benefit management services to covered individuals residing in Oklahoma;

(3) Directly or indirectly acting as an agent for, or otherwise representing or aiding on behalf of another, any person or PBM in:

(A) the solicitation, negotiation, procurement, or effectuation of pharmacy benefits management contracts or services to citizens of this state;

(B) the transaction of matters subsequent to effectuation of a contract providing pharmacy benefits management services and arising out of it; or

(C) any other manner representing or assisting a person in the transaction of the business of pharmacy benefits management to residents in this state.

(c) The provisions of this section do not apply to transactions in this state involving a contract between a covered entity and a PBM not contracted to any provider in this state, that is lawfully solicited, written, and delivered outside of this state, covering only pharmacy benefits provided to individuals or entities not residing or located in this state.

365-25-29.12. Commissioner's authority – advisory committee

(a) Pursuant to 36 O.S. § 6966, the Insurance Commissioner shall establish an advisory committee composed of representatives from the following constituent groups:

(1) Oklahoma Pharmacists Association;

(2) Office of the Oklahoma Attorney General;

(3) Consumers; and,

(4) Insurers or PBMs.

(b) The advisory committee shall function in an advisory capacity only. Any investigation or enforcement action in consequence of the act shall be at the sole discretion of the Commissioner.

(c) Nominees for members of the advisory committee as provided in § 6966 (C) shall be representative of the interests of the stakeholders listed above and shall be submitted to the Commissioner for appointment.
(d) Because committee members will be dealing with confidential, proprietary, or competitively sensitive information the Commissioner shall implement the following protections to prevent such information from being viewed or used inappropriately:

(1) Advisory committee members shall avoid conflicts of interest and recuse themselves from being involved in any proceedings where they may have insight into a competitor's pricing or proprietary information. The committee members must also avoid any conduct which could be viewed as a conspiracy to fix prices or otherwise restrict competition.

(2) Committee members shall be required to sign conflict of interest forms that disclose potential conflicts before serving on the committee, and affirmatively recuse themselves when a potential conflict arises. A conflict arises when a committee member has a financial stake in the outcome of a complaint or issue before the committee, or has an existing contract with a PBM, pharmacy, or insurer that is the subject of the committee's review. In addition, committee members shall be required to sign confidentiality commitments that acknowledge the statutory prohibition of any disclosure of confidential information that is available to the committee.

(3) All committee nominations must be supported by a National Association of Insurance Commissioners biographical affidavit and background check.

(e) Meetings of the advisory committee shall be convened by the Commissioner upon ten (10) days prior written notice or waivers thereof. The Commissioner or Commissioner's designee may attend any or all meetings of the committee.

365:25-29-13. Claims payment

Payment of claims arising under the terms and conditions of any policy of a medical insurance health benefit plan is the obligation of the insurer that issues such policy. Failure to properly handle such claims is addressed by other provisions of Title 36.

365:25-29-14. Inquiry/complaint handling process

(a) Complaints alleging failure by the PBM to comply with the act, shall be made in writing to the Commissioner, supported by evidentiary materials. All complaints must include a completed "PBM Complaint Form" as promulgated by the Commissioner.
(b) All audits of PBMs by health insurers shall include a review of complaints against the PBM to determine compliance with the terms of the contract between the PBM and the complainant.
(c) PBMs must provide the complainant with a written notice as to the final disposition of the complaint.
(d) As part of its response to the Department in connection with every complaint, the PBM must provide a statement to the Department that the complaint was carefully reviewed and could not be resolved under the terms and conditions of the contract.

365:25-29-15. Examinations of PBMs and health insurers

(a) Pursuant to 36 O.S. § 6965, the Commissioner may examine PBMs for compliance with the 59 O.S §§ 357-360 and 36 O.S. §§ 6958-6968.
(b) Pursuant to 36 O.S. § 309.1 through 309.7, the Commissioner may examine health insurers for compliance with 36 O.S. §§ 6958-6968.

(c) Any examination permitted under 36 O.S.§ 6965 will follow the examination procedures and requirements applicable to insurers under 36 O.S. §§309.1 through 309.7.
(d) The Commissioner shall not be required to regularly examine a PBM under the same time constraints, as required under 36 O.S. §§ 309.1 through 309.7, applicable to insurers, however, the Commissioner may examine the PBM, pursuant to 36 O.S. § 6965, at any time, in which he or she believes it reasonably necessary to ensure compliance with 59 O.S §§ 357-360 and 36 O.S. §§ 6958-6968 or provisions of this subchapter.