ARKANSAS REGISTER

Transmittal Sheet

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Effective Date _____ Code Number _____

Name of Agency Arkansas Insurance Department

Department Arkansas Department of Commerce

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Statutory Authority for Promulgating Rules Ark. Code Ann. §25-15-2023(a)

Rule Title: Final Rule 118 Pharmacy Benefit Managers Regulation

Intended Effective Date (Check One)		**Date**
☐ Emergency (ACA 25-15-204)	Legal Notice Published	7/14, 7/15, 7/16
☑ 10 Days After Filing (ACA 25-15-204)	Final Date for Public Comment	10/10/2024
☐ Other _____ (Must be more than 10 days after filing date.)	Reviewed by Legislative Council	11/15/2024
	Adopted by State Agency	11/19/2024

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

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Contact Person	**E-mail Address**	**Date**

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Clara Mezza
Signature

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Administrative Analyst
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11/19/2024
Date

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the rule.

RULE 118 PHARMACY BENEFITS MANAGERS REGULATION

Section 1. Authority

(A) This rule is issued pursuant to Ark. Code Ann. § 23-61-108(a)(1), § 17-92-507, and § 23-92-501 et seq., the Arkansas Pharmacy Benefits Manager Licensure Act, (hereafter, the "PBM Licensure Act"). The PBM Licensure Act authorizes the Arkansas Insurance Commissioner ("Commissioner") to issue rules to regulate the licensure and activities of pharmacy benefits managers ("PBMs").

(B) The Commissioner is authorized to issue rules establishing the licensing, fees, application, financial standards, penalties, compliance and enforcement, and reporting requirements of PBMs subject to the PBM Licensure Act. In addition, under Ark. Code Ann. § 23-92-509, the Commissioner is authorized to issue rules governing the financial solvency, network adequacy, maximum allowable cost practices, compensation, rebates and other matters of PBMs subject to the PBM Licensure Act.

(C) Pursuant to Act 665 of 2021, the Commissioner is authorized to issue a rule on the Pharmacy Audit Bill of Rights. Finally, the Commissioner is authorized to issue Rules

setting penalties or fines including monetary fines against PBMs under Ark. Code Ann. § 23-92-509(b)(1).

Section 2. Purpose

The purpose of this rule is to implement the PBM Licensure Act and to provide licensing, reporting and activity standards for PBMs which provide claims processing services or other prescription drug or device services, or both, for health benefit plans.

Section 3. Applicability & Scope

The provisions of this rule shall apply to all PBMs administering or transacting pharmacy benefits plan or programs for health benefit plans to residents of this State.

Section 4. Definitions

As used in this rule:

(1) "Adverse impact" means:

(A) the participation of pharmacies is reduced by 10% or more within the distance compliance requirements as specified in Rule 118 (7)(A); and

(B) the reduction in participation is solely due to a reduction in the compensation or reimbursement to a pharmacy.

(2) "Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include:

(A) Receiving payments for pharmacist services;

(B) Making payments to pharmacists or pharmacies for pharmacist services; or

(C) Both subdivisions (A) and (B) of this section.

(3) "Commissioner" means the Arkansas Insurance Commissioner.

(4) "Department" means the Arkansas Insurance Department.

(5)(A) "Health benefit plan" means any individual, blanket, or group plan, policy, or contract for healthcare services issued or delivered by a Healthcare Payor to residents of this state, including any group plan, policy, or contract for healthcare services issued outside this state that provide benefits to residents of this state.

(B) "Health benefit plan" does not include:

(i) Accidental-only plans;

(ii) Specified disease plans;

(iii) Disability income plans;

(iv) Plans that provide only for indemnity for hospital confinement;

(v) Long-term care only plans that do not include pharmacy benefits;

(vi) Other limited-benefit health insurance policies plans; or

(vii) Health benefit plans provided under Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.; and

(viii) Medicare Advantage plans or Medicare programs which provide pharmacy or prescription drug coverage.

(a) However, to the extent as permitted under federal law, such plans shall be included within the definition of health benefit plan, if the United States Supreme Court, or in the absence of such a ruling, the Eighth Circuit Court of Appeals, rules that such plans are subject to state regulation, with such regulation specific only to the authorities granted by the ruling court; and

(b) Should such a ruling occur and these plans become subject to regulation by the Department, the Department shall enforce any applicable law or regulation only against plans managed pursuant to contracts executed after the effective date of such ruling.

(6) "Healthcare Payor" means "Healthcare Payor" as defined by Ark. Code Ann. § 23-92-503(3).

(7) "Healthcare insurer" means an insurance company, a health maintenance organization, or a hospital and medical service corporation.

(8) "Maximum Allowable Cost ("MAC") law" or "MAC law," shall mean the requirements of Ark. Code Ann. § 17-92-507 for PBMs which are administering pharmacy benefits for a Health benefit plan of a Healthcare insurer.

(9) "Other prescription drug or device services" means services other than claims processing services, provided directly or indirectly, whether in connection with or separate from claims processing services, including without limitation:

(A) Negotiating rebates, discounts, or other financial incentives and arrangements with drug companies;

(B) Disbursing or distributing rebates;

(C) Managing or participating in incentive programs or arrangements for pharmacist services;

(D) Negotiating or entering into contractual arrangements with pharmacists or pharmacies, or both;

(E) Developing formularies;
(F) Designing prescription benefit programs; or
(G) Advertising or promoting services.

(10) "Pass-through pricing" means the model of prescription drug pricing in which a PBM charges the Health benefit plan the amount it actually pays a pharmacy for prescription drug or device services plus an administrative fee charged on a per prescription or per member basis.

(11) "Pharmacist" means an individual licensed as a pharmacist by the Arkansas State Board of Pharmacy.

(12) "Pharmacist services" means products, goods, and services, or any combination of products, goods, and services, provided as a part of the practice of pharmacy as defined in § 17-92-101.

(13) "Pharmacy" means the same as defined in Ark. Code Ann. § 17-92-101.

(14)(A) "Pharmacy benefits manager," or "PBM," means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a PBM, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans.

(B) "Pharmacy benefits manager" does not include any:

(i) Healthcare facility licensed in Arkansas;

(ii) Healthcare professional licensed in Arkansas;

(iii) Consultant who only provides advice as to the selection or performance of a PBM; or

(iv) Entity that provides claims processing services or other prescription drug or device services for the fee-for-service Arkansas Medicaid Program only in that capacity.

(15) "PBM affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager.

(16) "PBM network" means a network of pharmacists or pharmacies that are offered by an agreement or insurance contract to provide pharmacist services for health benefit plans.

(17) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services under a health benefit plan.

(18) "Pharmacy services administrative organization," or "PSAO," means an organization that helps community pharmacies and PBMs or third party payors achieve administrative efficiencies, including contracting and payment efficiencies.

(19)(A) "Rebate" means a discount or other price concession based on utilization of a prescription drug that is paid by a manufacturer or third party, directly or indirectly, to a PBM, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

(B) "Rebate" includes without limitation incentives, disbursements, and reasonable estimates of a volume-based discount.

(20) "Third party" means a person, business, or entity other than a PBM that is not an enrollee or insured in a health benefit plan.

(21) "Rule 106" means Arkansas Insurance Department Rule 106, "Network Adequacy Requirements for Health Benefit Plans."

(22) "Spread pricing" means the model of prescription drug pricing in which the PBM charges a Health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the PBM pays the pharmacy.

Section 5. Licensure & Financial Requirements

(A) Initial License. An applicant for a PBM license shall apply for a license on a form prescribed by the Commissioner. Each application for a license shall be verified by an officer or authorized representative of the applicant. The Commissioner shall require the PBM to describe or provide:

(1) A non-refundable filing fee of one thousand dollars ($1,000);

(2) The following evidence of financial responsibility: a cash surety bond issued by a corporate surety authorized to issue surety bonds in the State of Arkansas, in the sum of $1,000,000.00, which shall be subject to lawful levy of execution by any party to whom the licensee has been found to be legally liable;

(3) Contact information, including name, title, mailing address, email address, and direct phone number, for the following individuals (the PBM may instead provide the departmental contact name, mailing address, email address and direct phone number):

(a) MAC and National Average Drug Acquisition Cost ("NADAC") Complaints Contact or Contacts for AR;

(b) PBM Licensing Contact for AR; and

(c) Government Relations Contact for AR; and

(4) Proof of registration with the Arkansas Secretary of State;

(5) A list of the names, addresses and official positions of the persons who are to be responsible for the conduct of the affairs of the applicant, including all members of the board of the directors, board of trustees, executive committee, or other governing board or committee, the principal officers in the case of a corporation, and the partners or members in the case of a partnership or association;

(6) A copy of the basic organizational document of the applicant, such as the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents, and all amendments thereto; a copy of the bylaws, rules and regulations or similar document, if any, regulating the conduct of the internal affairs of the applicant;

(7) A copy of the applicant's standard, generic contract template, provider manual or other appropriate items incorporated by reference which it uses for contracts entered into by the applicant with pharmacists, pharmacies or pharmacy services administrative organizations in this State in administration of pharmacy benefits for Healthcare insurers, for the purpose only of the Department's review that such contracts comply with Ark. Code Ann. §§ 23-92-506(b), 23-92-506(c), 23-92-507, 4-88-1004 and 17-92-507;

(8) A copy of the applicant's most recent fiscal year-end audited financial statement;

(9) A description of the projected population or numbers of enrollees or beneficiaries to be administered by the applicant in this State to be serviced on an annual basis for all Healthcare insurers with whom the applicant has contracted, and, if applicable, the population or numbers of enrollees administered by the applicant in the previous year for a Healthcare insurer (please identify the numbers of enrollees by Healthcare insurer);

(10) The policy and procedure(s) which demonstrate that the applicant has compliant processes established to adhere to all of the requirements in Ark. Code Ann. § 17-92-507, concerning MAC Lists, and a description, including any written policies or procedures describing the appeals dispute resolution process for in-network or contracted pharmacists or pharmacies;

(11) A description or statement explaining how the applicant is in compliance with Ark. Code Ann. § 23-92-507, concerning Anti-Gag clauses, in its contracts with pharmacists or pharmacies in administration of pharmacy benefits for Health benefit plans issued by Healthcare insurers in this State;

(12) A description of the applicant's network's service areas by county in this State for a Healthcare insurer and the applicant's pharmacy provider directory list for a Healthcare insurer (this requirement may be satisfied if such information is submitted to the Department by the Healthcare insurer for the Healthcare insurer's network adequacy requirements);

(13) A statement of whether the applicant has been refused a registration, license or certification to act as (or provide the services of) a PBM or third party administrator, or has any registration, license or certification to act as such been denied, suspended, revoked or non-renewed for any reason by any state or federal entity (if so, attach specific details separately for each refusal or denial, including the date, nature and disposition of the action);

(14) A description of whether the applicant had a business relationship with an insurance company terminated for any alleged fraudulent or illegal activities in connection with the administration of a pharmacy benefits plan (if so, attach specific details separately explaining this termination, including the date, and nature of the termination); and

(15) Any other information which is deemed necessary by the Commissioner in evaluating the application to comply with the PBM Licensure Act or requirements of this Rule.

(B) Review and Approval of Initial Licensure Applications.

Upon receipt of a complete application for items required under Section (5)(A) of this Rule, the Commissioner shall review the application and:

(1) Approve the application and issue the applicant a PBM license; ~~or~~

(2) Notify the applicant in writing that the application is incomplete and that additional information is needed to complete the review of the application (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); or

(3) Deny the application. If the Commissioner determines that the applicant does not meet the requirements for licensure, the Commissioner shall:

(a) Provide written notice to the applicant that the application has been denied stating or explaining the basis of the denial; and

(b) Advise the applicant that a request for a hearing may be filed with the Commissioner in accordance with Ark. Code Ann. § 23-61-303.

(C) Renewal.

(1) A PBM license shall be renewed annually. A renewal application shall require the following:

(a) Proof that the PBM has in place the surety bond financial responsibility requirement in Section 5(A)(2) of this Rule; and

(b) Documentation of any changes to the items in Section 5(A) of this Rule from the date the PBM became licensed or last renewed its license.

(2) The Department's review of renewal documents shall also include review of whether the PBM timely and compliantly filed any applicable statutorily required reports and certifications for the year immediately preceding submission of the renewal application;

(3) A renewal application shall be deemed approved by the Commissioner after forty-five (45) days from the date of the receipt of the complete renewal application by the Department, unless denied or disapproved by the Commissioner during that time period. For disapprovals or denials of a renewal licensure by the Commissioner, the Commissioner shall:

(a) Provide written notice to the renewal PBM applicant that the licensure renewal was denied stating or explaining the basis of the denial; and

(b) Advise the PBM renewal applicant that a request for a hearing may be filed with the Commissioner in accordance with Ark. Code Ann. § 23-61-303.

(D)(1) Standards of Review. The Commissioner shall deny an initial application for licensure or deny renewal of a PBM license for the following reasons:

(a) The Commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not competent, trustworthy, financially responsible, or of good personal and business reputation as to its directors or officers;

(b) The Commissioner determines that the magnitude of violation or non-compliance demonstrated by the PBM warrants denial of licensure; or

(c) The PBM has failed to timely submit information to complete review of the application under Section (5)(B)(2) or has failed to submit a renewal application and information under Section (5)(C).

(2) In lieu of a denial for an initial licensure or renewal application, the Commissioner may permit the PBM to submit to the Commissioner a corrective action plan to cure or correct deficiencies under (5)(D)(1) of this Rule.

(E) Cash surety bond. A cash surety bond under 5(A)(2) of this Rule shall be maintained at all times by the PBM during its licensure with the Department. The Commissioner may however reduce the amount of the bond requirement in Section 5(A)(2) if the amount required is unreasonable relative to the size of the PBM's business operations in this State and would cause a significant financial hardship.

(F) Confidentiality. The information submitted by a PBM under Section 5(A)(6) through (15) of this Rule shall be considered confidential under Ark. Code Ann. §§ 23-61-103, 23-61-107(a)(4), and 23-61-207, and, in addition, shall be considered proprietary, as information which would provide unfair competitive advantage to a competitor, under the Freedom of Information Act of 1967, in Ark. Code Ann. § 25-19-105(b)(9). A PBM shall file with the Department, at the time of its licensure filing, a redacted, public version of its application, excepting any proprietary information, required to be submitted to the Department under this Rule.

Section 6. Contract Review

(A) Contract Review.

(1) Prohibited Contract Language. No contract entered into by a PBM and a pharmacist or pharmacy which relates to participation or administration of a Pharmacy benefits plan or program of a Health benefit plan shall contain language in violation of Ark. Code Ann. §§ 23-92-506(b)(5)(A) [NADAC], 23-92-506(c) [payment retroactivity], 23-92-507 [anti-gag clauses], 4-88-1004 [anti-clawback], and 17-92-507 [maximum allowable cost].

(2) Waiver Prohibited. The provisions in, §§ 23-92-506(b)(5)(A) [NADAC], 23-92-506(c) [payment retroactivity], 23-92-507 [anti-gag clauses], 4-88-1004 [anti-clawback] and 17-92-507 [maximum allowable cost] may not be waived by contract. The provisions in Ark. Code Ann. § 23-92-506(b) [fees and standards] may be modified by contract if the fees or standards are permitted by the Commissioner under Section (6)(A)(3) of this Rule.

(3) Review of Contractual Language under Ark. Code Ann. §§ 23-92-506(b)(2) [fees] and 23-92-506(b)(3) [certification standards]. No contract entered into by a PBM and a pharmacist or pharmacy which relates to participation or administration of a Pharmacy benefits plan or program of a Health benefit plan shall contain language in violation of Ark. Code Ann. § 23-92-506(b)(2) or 23-92-506(b)(3) unless such provisions have been reviewed and approved by the Commissioner pursuant to this Section.

(a) A PBM may submit to the Commissioner for review and approval contractual language permitting fees or certification standards, otherwise prohibited under Ark. Code Ann. §§ 23-92-506(b)(2) and 23-92-506(b)(3), by providing a written justification or explanation to the Commissioner for the fee or standard. For approval of such provisions, it shall be the obligation of the PBM to provide objective evidence, rather than conclusory statements, that the fee or standard is necessary to: (1) control costs of the PBM or Health benefit plan; or (2) maintain quality measures of the PBM or Health benefit plan.

(b) Upon receipt of the request for approval and written justification, the Commissioner shall review such provisions and shall provide the PBM with a written response indicating approval or disapproval of such language, or may request more information, within forty-five (45) days. A disapproval shall explain the basis of the disapproval. The PBM may supplement its written justification during the period of review by the Department. If the Commissioner disapproves the provision(s), the PBM may request a hearing with the Commissioner in accordance with Ark. Code Ann. § 23-61-303. The administrative hearing under this Section shall be restricted as to whether the fee or standard meets the requirements of Section 6(A)(3)(a) of this Rule.

(B) Marketing and Advertising. Pursuant to Ark. Code Ann. § 23-92-506(b)(1), a PBM shall not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading. The Commissioner shall enforce this requirement as he or she similarly enforces the requirements of Ark. Code Ann. § 23-66-206(6) and (7) including applying the applicable penalties, for violations, under Ark. Code Ann. § 23-66-210. The Commissioner shall not pre-review or pre-approve a PBM's marketing documents or advertising statements prior to use by the PBM in this State market; however, the Commissioner shall instead review and enforce this subdivision of this Section on a per complaint basis, and therefore, it shall be the responsibility of the PBM at all times to ensure that its marketing and advertising is truthful and not misleading.

Section 7. Pharmacy Network Adequacy and Compensation

The provisions of this Section shall apply to healthcare insurers and healthcare payors, and PBMs administrating for such health benefit plans, as defined in Ark. Code Ann. § 23-92-503(2) and (3) to the extent as permitted by federal law.

(A) Pharmacy Network Adequacy.

(1) In order to effectively implement Ark. Code Ann.§ 23-92-505, because a PBM is actually administrating a Health benefit plan for a Healthcare insurer, as contracted by the PBM with a Healthcare insurer, the Commissioner hereby maintains that a pharmacy network is adequate if the pharmacy network meets the network adequacy distances in

Section 7(A)(2) of this Rule. A Healthcare insurer shall therefore file and report its pharmacy network subject to Rule 106 requirements applicable to primary care professionals in lieu of any reporting obligations of the PBM under Ark. Code Ann. § 23-92-505(a)(2). For purposes of this reporting, pursuant to Ark. Code Ann. § 23-92-505(a)(1)(B) and Ark. Code Ann. §23-92-509(b)(2)(B), mail-order pharmacies shall not be included in the calculations determining network adequacy for pharmacists or pharmacies.

(2) The network adequacy requirements applicable to pharmacies shall adhere to the standards in Ark. Code Ann. § 23-92-509(b)(2)(B).

(B) Compensation.

(1) Pursuant to Ark. Code Ann. § 23-92-506(a)(1), the Commissioner may, in his or her discretion, review a PBM's reimbursement program or compensation for a Pharmacy benefit plan of a Healthcare insurer to determine if the reimbursement is fair and reasonable to provide an adequate Pharmacy benefits network for a Health benefit plan. A Healthcare insurer using a PBM for administration of pharmacy benefits shall reasonably ensure that the reimbursement or compensation of pharmacists or pharmacies does not adversely impact participation of pharmacists or pharmacies in its Health benefit plans.

(2)(a) The Commissioner shall not review reimbursement complaints or concerns under this Section on a case-by-case basis for a pharmacist or pharmacy. The Commissioner's discretion to review pharmacy compensation programs pursuant to this Section, shall be guided by the following factors:

(i) Whether the compensation or reimbursement program adversely impacts pharmacist or pharmacy participation in a Health benefit plan; and

(ii) The extent to which the compensation or reimbursement program has an impact on pharmacist or pharmacy participation in Health benefit plans either on a state-wide basis, or in a significant geographical area of the State.

(b) For purposes of this Section, the Commissioner may consider a pharmacist's or pharmacy's declination to provide covered prescription drugs under Ark. Code Ann. § 17-92-507(e) as a circumstance negatively impacting participation, because, in this instance, the Health benefit plan is unable to provide its covered member with a covered prescription drug through one of its in-network pharmacists or pharmacies.

(c) A Healthcare insurer or Payor using a PBM for administration of pharmacy benefits shall take the following measures:

(i) Develop a mechanism or system with its PBM to track or monitor, on an annual basis, the number of declinations under Ark. Code Ann. § 17-92-507(e);

(ii) Develop a mechanism or system with its PBM to track or monitor, on an annual basis, the number of pharmacists or pharmacies which terminated their network participation with the Healthcare insurer or PBM network due to reduction in compensation; and

(iii) Report such information to the Arkansas Insurance Department's Regulatory Healthlink Division on an annual basis, as part of the Healthcare insurer's Payor's network adequacy filings.

(d) In addition, for purposes of this Section, for generic, prescription drugs subject to MAC requirements, the Commissioner may additionally consider the extent or magnitude to which a PBM has adjusted a pharmacist's or pharmacy's reimbursement pricing, on the average on a quarterly basis, to comply with Ark. Code Ann. § 17-92-507(c)(4)(C)(iii), as a circumstance negatively impacting participation, because, in these instances, it is reasonable to conclude that a pharmacist or pharmacy's decision to continue in participation, at a negative cost or negative reimbursement, or pattern, adversely impacts a pharmacist's or pharmacy's prospective participation with the Health benefit plan.

(3) The provisions in Section 7(B)(2) of this rule are guidelines for the Commissioner's discretion to review pharmacy compensation or reimbursement programs under network adequacy requirements, and therefore, the existence of any of the circumstances in that Section, do not automatically mandate or require the Commissioner to review pharmacy compensation or reimbursement programs.

(4) The Arkansas Insurance Department's Regulatory Healthlink Division shall develop a system to gather the information required in Section 7(B)(2) of this Rule.

(5) In the event the Commissioner decides to review compensation or reimbursement under this Section, he or she shall be restricted to reviewing the reimbursement program for purposes of compliance with Rule 106 network adequacy standards. In his or her review of compensation under this Section, the Commissioner may review or examine either the Healthcare insurer Payor or PBM, or both, under the examination standards or procedures under Ark. Code Ann. §§ 23-61-201, et. seq. If after review or examination, the Commissioner determines a network adequacy violation exists due to adverse impact on Pharmacy participation, it shall be the responsibility of the Healthcare insurer, using a PBM for administration of pharmacy benefits of its Health benefit plans, to take corrective actions to avoid any penalties under Section 7 of Rule 106.

(6) Confidentiality. Any information obtained by the Commissioner, from a review, investigation or examination of compensation under this Section shall be considered

confidential under Ark. Code Ann. §§ 23-61-103, 23-61-107(a)(4), and 23-61-207 and, in addition, shall be considered proprietary, as information which would provide an advantage to a competitor, under the Freedom of Information Act of 1967, in Ark. Code Ann. § 25-19-105(b)(9).

(C) Compensation or Reimbursement Requirements Regardless of Network Adequacy. Pursuant to Ark. Code Ann. §§ 23-92-506(b)(4) and 17-92-507, a PBM shall not reimburse a pharmacy or pharmacist in the state in an amount less than the amount that the PBM reimburses a PBM affiliate for providing the same pharmacist services. The amount shall be calculated on a per-unit basis using the same generic product identifier or generic code number.

Section 8. Examinations of PBMs and Healthcare Payors.

The provisions of this Section shall apply to healthcare insurers and healthcare payors as defined in Ark. Code Ann. § 23-92-503(2) and (3), and PBMs administrating for such health benefit plans, to the extent as permitted by federal law.

(A) Pursuant to Ark. Code Ann. § 23-92-508, the Commissioner may examine the affairs of a PBM for compliance with the requirements of the PBM Licensure Act or requirements of this Rule. In addition, the Commissioner may examine the affairs of a Healthcare Payor subject to the requirements of Section 7 of this Rule.

(B) Any examination permitted under this Section shall follow the examination procedures and requirements applicable to Healthcare Payors under Ark. Code Ann. §§ 23-61-201 et seq, including but not limited to the confidentiality provisions under Ark. Code Ann. § 23-61-207.

(C)(1) A PBM shall not be regularly examined under the same time periods of insurers as required under Ark. Code Ann. § 23-61-201(a)(2), however, the Commissioner may examine the PBM or Healthcare Payor, pursuant to this Section, at any time, in which he or she believes it reasonably necessary to ensure compliance with the PBM Licensure Act or provisions of this Rule.

(2) The Insurance Commissioner's examination authorities include authority to examine the books and records of a PBM as necessary to determine:

(a) The aggregate amount of rebates received by a PBM;

(b) The aggregate amount of rebates distributed by a PBM to an appropriate healthcare payor;

(c) The aggregate amount of rebates passed on to an enrollee of each healthcare payor at the point of sale that reduced the enrollee's applicable deductible, copayment, coinsurance, or other cost sharing amount;

(d) The individual and aggregate amount paid by a healthcare payor to a PBM for pharmacist services itemized by pharmacy, product, and goods and services, including other prescription drug or device services; and

(e) The individual and aggregate amount a PBM paid for pharmacist services itemized by pharmacy, products, and goods and services, including other prescription drug or device services.

Section 9. Reporting Requirements

The provisions of this Section shall apply to healthcare insurers and healthcare payors as defined in Ark. Code Ann. § 23-92-503(2) and (3), and PBMs administrating for such health benefit plans, to the extent as permitted by federal law.

(A) State Funded Payments Fair Disclosure Reporting.

(1) The following provisions in this Section shall apply to PBMs subject to Act 769 of 2009 in the "Fair Disclosure of State Funded Payments for Pharmacists' Services Act," codified in Ark. Code Ann. § 4-88-801 et seq., if the PBM is administering pharmacy benefits for a Healthcare insurer issuing Health insurance benefit plans, as defined under Ark. Code Ann. § 23-61-1003.

(2) For purposes of compliance with Ark. Code Ann. § 4-88-803(d), a PBM subject to 9(A)(1) shall file a report with the Commissioner containing a statement indicating whether the PBM charges the health benefit plan a higher amount for pharmacist services than what it provides to the pharmacy or pharmacists providing those services.

(3) Pursuant to Ark. Code Ann. § 4-88-803(d)(2), any annual report submitted under that provision or under this Section shall be considered proprietary and confidential under Ark. Code Ann. § 23-61-207 and not subject to the Freedom of Information Act of 1967, under Ark. Code Ann. § 25-19-101 et seq.

(4) The report required under this Section shall be due annually on the date each year in which Healthcare insurers are required to file a request for approval of premium rates in the fully insured market. The report shall provide the pricing and reimbursement information as required under this Section for the preceding plan year.

(B) Fairness in Cost Sharing Report (Act 965 of 2021).

(1) Health insurers and health maintenance organizations in the fully insured market shall file or shall jointly coordinate with their PBM to annually file a report with the Commissioner as required by Act 965 of 2021, the "Arkansas Fairness in Cost Sharing Act," codified at Ark. Code Ann. § 23-79-2301 et seq.

(2) The annual report shall describe "plan-specific information related to savings and accountability to document how enrollees are realizing a cost savings under each plan" and shall be due January 1 of each calendar year.

(3) The report shall be filed in any format required by the Commissioner, but in the absence of such requirement, shall be filed in a narrative form.

(C) Arkansas Pharmacy Benefits Manager Share the Savings Act (Act 333 of 2023).

(1) A PBM shall submit a certification to the Insurance Commissioner by January 1 of each calendar year certifying that the PBM has complied with the requirements of Act 333 of 2023, codified at Ark. Code Ann. § 23-92-704 et seq., during the previous calendar year.

(2) The certification shall be signed by the chief executive officer or chief financial officer of the PBM and shall be in a format approved or established by the Commissioner.

(3) The certification shall include the PBM's best estimate of the aggregate amount of rebates used to reduce enrollee-defined cost sharing for prescription drugs in the previous calendar year based on information known to the PBM as of the date of the certification.

Section 10. MAC Recordkeeping Requirements

The provisions of this Section shall apply to healthcare insurers and healthcare payors as defined in Ark. Code Ann. § 23-92-503(2) and (3), and PBMs administrating for such health benefit plans, to the extent as permitted by federal law.

(A) The following provisions of this Section shall apply to any PBM subject to Ark. Code Ann. § 17-92-507 (hereafter, the " MAC law") that administers pharmacy benefits for a Health benefit plan of a Healthcare insurer.

(B) To reasonably ensure compliance with the MAC law, a PBM subject to Section 10 of this Rule shall develop a record keeping system to track, monitor and record the following

information, to be aggregated on a quarterly basis, for the purpose of providing information to the Department, upon request by the Department:

(1) The number of challenges or appeals the PBM received under the MAC law;

(2) The outcomes of the challenge or appeal, whether denied or upheld by the PBM;

(3) The number of times the PBM provided pricing information pursuant to Ark. Code Ann. § 17-92-507(c)(4)(C)(ii) to a challenging pharmacy to demonstrate a drug subject to appeal could be acquired from a national or regional pharmaceutical wholesaler in stock at a price below the MAC list; and

(4) The total amount of reimbursement re-adjustment which occurred that quarter under Ark. Code Ann. § 17-92-507(c)(4)(C)(iii) and the average time period taken for such reimbursement adjustments.

(C) The report shall report aggregate numbers on a quarterly basis, and if submitted upon request by the Department, shall be considered a request for information under Ark. Code Ann. §§ 23-61-103(d) and 23-61-207, and shall be considered confidential.

Section 11. MAC Appeals

(A) In responding to a MAC complaint for complaints to AID, the PBM shall be subject to the same time period for responding to the complaint as described in Department Rule 43 for "health carriers."

(B) A pharmacy provider or a pharmacy services administrative organization ("PSAO") acting on the provider's behalf shall make reasonable efforts to exhaust any internal appeal requirements of the PBM prior to filing a complaint with the Department. However, a pharmacy provider shall not be required to exhaust internal appeal requirements of the PBM if a PBM has significantly failed to provide timely communication and timely processing of the appeal, as required under the MAC law, or has failed to abide by its MAC appeal processes as described in Section 5(A)(10) of this Rule.

(C) A PBM shall not be held responsible for failure to timely process a communication or timely process in the event that a PSAO or pharmacy has not submitted sufficient information for the PBM to process the appeal.

Section 12. Pharmacy Audit Bill of Rights

(A) PBMs shall comply with the "Arkansas Pharmacy Audit Bill of Rights."

(B) Notwithstanding any other law, when an audit of the records of a pharmacy is conducted by a managed-care company, an insurance company, a third-party payor, or any entity that represents responsible parties such as companies or groups, the audit shall be conducted in accordance with the following bill of rights:

(1) The entity conducting the initial on-site audit shall give the pharmacy notice at least one (1) week before conducting the initial on-site audit for each audit cycle;

(2) Any audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;

(3)(a)(i) Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not in and of itself constitute fraud.

(ii) However, a claim arising under subdivision (B)(3)(a)(i) of this section may be subject to recoupment.

(b) A claim arising under subdivision (B)(3)(a)(i) of this section is not subject to criminal penalties without proof of intent to commit fraud;

(4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(5)(a) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(b) However, recoupment of claims under subdivision (B)(5)(A) of this section shall be based on the actual overpayment unless the projection for overpayment or underpayment is part of a settlement by the pharmacy;

(6)(a) Where an audit is for a specifically identified problem that has been disclosed to the pharmacy, the audit shall be limited to claims that are identified by prescription number.

(b) For an audit other than described in subdivision (B)(6)(A) of this section, an audit shall be limited to twenty-five (25) prescriptions that have been randomly selected.

(c) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site.

(d) Except for audits initiated under subdivision (B)(6)(A) of this section, an entity shall not initiate an audit of a pharmacy more than two (2) times in a calendar year;

(7)(a) A recoupment shall not be based on:

(i) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Arkansas State Board of Pharmacy; or

(ii)(A) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the Arkansas State Board of Pharmacy.

(B) This subdivision (B)(7) applies only to audits of claims submitted for payment on or after January 1, 2012.

(b) Subdivisions (B)(7)(a)(i) and (ii) of this section do not apply in cases of United States Food and Drug Administration regulation or drug manufacturer safety programs;

(8) Recoupment shall only occur following the correction of a claim and shall be limited to amounts paid in excess of amounts payable under the corrected claim;

(9) Except for Medicare claims, approval of drug, prescriber, or patient eligibility upon adjudication of a claim shall not be reversed unless the pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements;

(10) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(11) A pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(12) The period covered by an audit shall not exceed twenty-four (24) months from the date the claim was submitted to or adjudicated by a managed-care company, an insurance company, a third-party payor, or any entity that represents such companies or groups;

(13) Unless otherwise consented to by the pharmacy, an audit shall not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled during that time;

(14)(a) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty (120) days after conclusion of the audit.

(b) A final audit report shall be delivered to the pharmacy within six (6) months after receipt of the preliminary audit report or the final appeal as provided for in subsection (C) of this section, whichever is later; and

(15) Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(C) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (D) of this section.

(D)(1) Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(2) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further proceedings.

(E) Each entity conducting an audit shall provide a copy of the final audit report to the plan sponsor after completion of any review process.

(F)(1) The full amount of any recoupment on an audit shall be refunded to the responsible party.

(2) Except as provided in subdivision (F)(3) of this section, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

(3) Subdivision (F)(2) of this section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both the following conditions are met:

(a) The responsible party and the entity have a contract that explicitly states the percentage charge or assessment to the responsible party; and

(b) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly on amounts recouped.

(G) This section does not apply to any audit, review, or investigation that involves alleged fraud, willful misrepresentation, or abuse, including without limitation:

(1) Medicaid fraud as defined in Ark. Code Ann. § 5-55-111;

(2) Abuse or fraud as defined in Ark. Code Ann. § 20-77-1702; or

(3) Insurance fraud.

Section 13. Compliance with Bulletins

In addition to compliance with statutory and regulatory authorities applicable to PBMs, PBMs shall reasonably strive to follow all standards announced by the Commissioner through publication of bulletins.

Section 14. Penalties

The penalty provisions under this section apply to PBMs administrating health benefit plans or for healthcare payors under § 23-92-503(2) and (3) that are permitted to be regulated by the State and are not prohibited from State regulation under federal law.

(A) After notice and opportunity for hearing, the Commissioner may:

(1) Impose a penalty of up to five thousand dollars ($5,000) per violation against a PBM if the Commissioner finds that the PBM has not:

(a) Followed the process established for determining pricing or costs under the MAC List under Ark. Code Ann. § 17-92-507; or

(b) Used the national average drug acquisition cost under Ark. Code Ann. § 23-92-506(b); or

(c) Complied with Ark. Code Ann. § 23-92-506(b)(4)(A); or

(2) Revoke or suspend the license of a PBM if the Commissioner finds that the PBM:

(a) Has committed a pattern of violations of this subchapter;

(b) Has not followed the process established for determining pricing and costs under the MAC List under Ark. Code Ann. § 17-92-507; or

(c) Has not used the national average drug acquisition cost under Ark. Code Ann. § 23-02-506(b).

(B) Pursuant to Ark. Code Ann. § 17-92-507, any violation of the Arkansas MAC Law is also a deceptive and unconscionable trade practice under the Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 et seq., and a prohibited practice under the Trade Practices Act, Ark. Code Ann. § 23-66-201 et seq.

(C) For all other violations of Ark. Code Ann. § 17-92-507, Ark. Code Ann. § 23-92-501 et seq., or Rule 118, not otherwise provided for in this Rule, the Commissioner may impose the penalties provided at Ark. Code Ann. § 23-60-108 or Ark. Code Ann. § 23-66-210.

Section 15. Provisions in Rule Applicable to All Healthcare Payors

Any language in the provisions of this Rule referring to or referencing requirements of an insurer, healthcare insurer, or health maintenance organization shall include health benefit plans issued or delivered by a Healthcare Payor to residents of this state as permitted by state or federal law.

Section 16. Severability

Any section or provision of this rule held by a court to be invalid or unconstitutional will not affect the validity of any other section or provision.

Alan McClain

ALAN MCCLAIN
INSURANCE COMMISSIONER

11-19-24

DATE