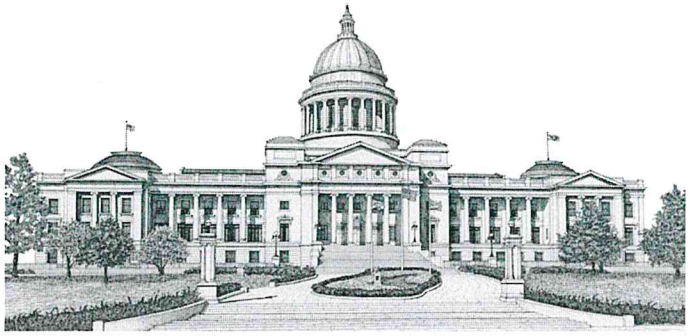
ARKANSAS REGISTER



Transmittal Sheet

Use only for **FINAL** and **EMERGENCY RULES**

Secretary of State
John Thurston
500 Woodlane, Suite 026
Little Rock, Arkansas 72201-1094
(501) 682-5070
www.sos.arkansas.gov

For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency Arkansas Insurance Department

Department Arkansas Department of Commerce

Contact Booth Rand, Managing Attorney E-mail booth.rand@arkansas.gov Phone 501-371-2820

Statutory Authority for Promulgating Rules Ark. Code Ann. §23-69-501 et seq and Act 1018 of 2021

Rule Title: Emergency Rule 118: Pharmacy Benefit Managers Regulations

Intended Effective Date (Check One)		**Date**
☑ Emergency (ACA 25-15-204)	Legal Notice Published	
☐ 10 Days After Filing (ACA 25-15-204)	Final Date for Public Comment	
☐ Other _____ (Must be more than 10 days after filing date.)	Reviewed by Legislative Council	6/14/2022
	Adopted by State Agency	6/16/2022

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

Clara D. Mezza	clara.mezza@arkansas.gov	6/16/2022
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

501-683-3497 clara.mezza@arkansas.gov
Phone Number **E-mail Address**

Insurance Administrative Coordinator
Title

6/16/2022
Date

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Insurance Department

DIVISION Legal Division

PERSON COMPLETING THIS STATEMENT Booth Rand

TELEPHONE 501-371-2820 **FAX** 501-371-2639 **EMAIL:** booth.rand@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Rule 118: PHARMACY BENEFITS MANAGERS REGULATION

1. Does this proposed, amended, or repealed rule have a financial impact? Yes ☐ No ☒

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes ☒ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

   If an agency is proposing a more costly rule, please state the following:

   (a) How the additional benefits of the more costly rule justify its additional cost;

   (b) The reason for adoption of the more costly rule;

   (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

   (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

NONE or NOT APPLICABLE.

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	

Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	n/a	Total	n/a

(b) What is the additional cost of the state rule?

NONE

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	n/a	Total	n/a

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

There should be no financial impact on small business.

Current Fiscal Year
$ _____

Next Fiscal Year
$ _____

---

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

NONE

Current Fiscal Year
$ _____

Next Fiscal Year
$ _____

---

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

NOT APPLICABLE

Yes ☐ No ☐

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
    (a) justifies the agency's need for the proposed rule; and
    (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
    (a) the rule is achieving the statutory objectives;
    (b) the benefits of the rule continue to justify its costs; and
    (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

EMERGENCY RULE 118

PHARMACY BENEFITS MANAGERS REGULATION

Section 1. Authority

This rule is issued pursuant to Ark. Code Ann. § 23-61-108(a)(1) and § 23-92-504(b)(1), the Arkansas Pharmacy Benefits Manager Licensure Act, (hereafter, the "PBM Licensure Act") authorizes the Arkansas Insurance Commissioner ("Commissioner") to issue rules to regulate the licensure and activities of pharmacy benefits managers ("PBMs") .The Commissioner is authorized to issue rules establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefits managers 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 as delineated in Ark. Code Ann. § 23-92-509 of pharmacy benefits managers subject to the PBM Licensure Act.

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 pharmacy benefit managers under Ark. Code Ann. § 23-92-509(b)(1).

This Rule is also issued pursuant to the authority vested in the Commissioner to issue Emergency Rules under Ark. Code Ann. §25-15-204(c). Immediate adoption of this Rule is

necessary to implement Act 665 of 2021 and to comply with court rulings on the applicability of the PBM Licensure Act to self-funded health plans, as well as immediately necessary to adopt PBM standards related to maximum allowable cost and National Average Drug Acquisition Cost ("NADAC") reimbursement bulletins recently issued by the Department, and to provide updated licensing standards for PBMs conducting business in this State. It is hereby declared that the adoption of this Rule is necessary to prevent imminent peril to the health, safety or welfare of the citizens of this State.

Section 2. Purpose

The purpose of this rule is to implement the PBM Licensure Act and to provide licensing, reporting and activity standards for pharmacy benefit managers 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 in this State.

Section 4. Definitions

As used in this rule:

(1) "Adverse impact" means:

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

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

(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 (1)(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 in 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;

(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 Pharmacy benefits manager charges the Health benefit plan the amount it actually pays a Pharmacist 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 § 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 pharmacy benefits manager, 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 pharmacy benefits manager;

(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) "Pharmacy benefits manager 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) "Pharmacy benefits manager 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 pharmacy benefits managers or third party payers 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 pharmacy benefits manager, 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; and

(20) "Third party" means a person, business, or entity other than a pharmacy benefits manager 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 Pharmacy benefit manager charges a Health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the Pharmacy benefits manager pays the Pharmacist. Spread pricing may also include an administrative fee charged to the Health benefit plan on a per prescription or per member basis.

Section 5. Licensure & Financial Requirements

A. Initial License and Renewal.

A PBM 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 $1,000.00;

(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) The name of the PBM, the contact information of the PBM, including electronic email, business address and phone number of the PBM, and name, address and contact information for the

principal contact person of the PBM for purposes of compliance with requirements by the Arkansas Insurance Department;

(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 PBM 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 PBM, 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 PBM's standard, generic contract template, provider manual or other appropriate items incorporated by reference which it uses for contracts entered into by the PBM 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 most recent fiscal year-end audited financial statement of the PBM;

(9) A description of the projected population or numbers of enrollees or beneficiaries to be administered by the PBM in this State to be serviced on an annual basis for all Healthcare insurers with whom the PBM has contracted, and, if applicable, the population or numbers of enrollees administered by the PBM 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 PBM has compliant processes established to adhere to all of the requirements in Ark. Code Ann. § 17-92-507, concerning Maximum Allowable Cost 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 PBM 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 PBM's network's service areas by county in this State for a Healthcare insurer and the PBM'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 or dishonest 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 Process.

1. For 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:

(A) approve the application and issue the applicant a PBM license; or

(B) 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

(C) deny the application. If the Commissioner determines that the PBM applicant does not meet the requirements for licensure, the Commissioner shall:

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

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

2. Renewal. A PBM license shall be renewed annually. A renewal application shall require proof that the PBM has in place the surety bond financial responsibility requirement in Section 5(A)(2) of this Rule, as well as require the PBM to submit to the Department any changes made to the items in Section 5(A) of this Rule from the date of its most recent licensure. 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.

3. Standards of Review. The Commissioner shall deny an initial application for licensure or deny renewal by a PBM for the following reasons:

(A) the PBM operates, or proposes to operate, in a financially hazardous condition relative to its financial condition and the services it administers, or proposes to administer for Healthcare insurers in this State; or

(B) the PBM has been determined by the Commissioner to be in violation or non-compliance with the requirements in this Rule or Arkansas state law; or

(C) the PBM has failed to timely submit information to complete review of the application under Section 5(B)(1)(b) or has failed to submit a renewal application and information under Section 5(B)(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 Section 5(B)(3)(A) or (C) of this Rule.

4. 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.

C. Confidentiality. The information submitted by a PBM under Section 5(A)(6) through (16) 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(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(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)(3) of this Rule.

3. Review of Contractual Language under Ark. Code Ann. §§ 23-92-506(b)(2) [fees1 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

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(2). For purposes of this reporting, pursuant to Ark. Code Ann. § 2392-505(1)(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. §23-99-509(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. For Healthcare insurers using PBMs for administration of pharmacy benefits of its Health benefit plans, a Healthcare insurer 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. 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:

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

(b) 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.

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. For Healthcare insurers Payors using PBMs for administration of pharmacy benefits of its Health benefit plans, the Healthcare insurers shall (1) 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); (2) 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 (3) 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. The reporting shall begin on and after March 1, 2019, or upon the 2019 date in which network adequacy reports are due for Healthcare insurers, whichever is later.

In addition, for purposes of this Section, for generic, prescription drugs subject to MAC requirements, the Commissioner may additionally consider the extent or magnitude in which a pharmacist's or pharmacy's reimbursement pricing has been adjusted, on the average on a quarterly basis, inventory costs under 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 information that 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. <u>Compensation or Reimbursement Requirements Regardless of Network Adequacy.</u>

1. Pursuant to Ark. Code Ann. §§ 23-92-506(b)(4) and 17-92-507, in no event, however shall a PBM reimburse a pharmacy or pharmacist in the state in an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager 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

A. Examination of PBMs and Healthcare Payors.

1. 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.

2. 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.

3. 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.

Section 9. Reporting Requirements

A. Maximum Allowable Cost Reporting.

1. The following provisions in this Section shall apply to PBMs subject to Ark. Code Ann. § 17-92-507 (hereafter, the "Maximum allowable cost law" or "MAC law") and who are administering pharmacy benefits for a Health benefit plan of a Healthcare insurer.

2. To reasonably ensure compliance with the Maximum allowable cost law, PBMs, subject to Section 9(A)(1) of this Rule, shall develop a record keeping system which shall track, monitor and record the following information, to be aggregated on a statistical quarterly basis, for the purpose of providing information to the Department, upon request by the Department:

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

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

(c) the number of times a challenging pharmacy obtained the pricing information in Ark. Code Ann. § 17-92-507(c)(4)(C)(ii) which allowed it to acquire the drug from a national or regional pharmaceutical wholesaler in stock at a price below the maximum allowable cost list;

(d) 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; and

(e) The report shall report aggregate numbers on a quarterly basis, and, if submitted upon the 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.

B. Pharmacy Provider Complaints Related to Maximum Allowable Cost Law Compliance under Ark. Code Ann. § 17-92-507.

1. The PBM shall designate the name, address, phone number, including an electronic mail contact, of the organization which shall be responsible for responding to the Department for complaints the Department has received from pharmacy providers for maximum allowable cost law alleged violations. In responding to the complaint, the PBM shall be subject to Rule 43, Section (11)(A), related to its time period for responding to the complaint.

2. A pharmacy provider or a pharmacy services administrative organization (PSAO) acting on their behalf shall make reasonable efforts to exhaust any internal appeal requirements of the PBM prior to the filing of 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 to the Department in Section 5(10) of this Rule. A PBM shall 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.

3. Pursuant to Ark. Code Ann. §17-92-507(g)(1), a violation of the Maximum Allowable Cost law, shall be subject to the penalties or fines or actions under Section 11 of this rule and considered a prohibited practice under the Arkansas Insurance Department's Trade Practices Act, Ark. Code Ann. § 23-66-201 et seq.

4. AID shall additionally coordinate with the Arkansas Attorney General's Office for referral to that Office of complaint cases which reasonably appear to show a pattern or practice of violations by a PBM.

C. 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; (1) administering pharmacy benefits for a Healthcare insurer issuing Health insurance benefit plans under the Arkansas Works Act of 2016, as defined under Ark. Code Ann. § 23-61-1003(5); and (2) engaged in Spread pricing for pharmacy benefits of a Healthcare insurer.

2. A PBM and Healthcare insurer, subject to Section 9(C)(1) of this Rule, shall jointly coordinate to facilitate the PBM's required filing of an annual report to the Commissioner as required under Ark. Code Ann. § 4-88-803(d). To reasonably ensure compliance with this requirement, the Commissioner may seek or request data from either the PBM or Healthcare insurer, or both, under a format developed by the Department, pursuant to a bulletin timely issued to PBMs and Healthcare insurers subject to Section 9(C)(1) of this Rule.

3. The Department shall make reasonable efforts to alternatively ascertain whether the required reporting data under Ark. Code Ann. §§ 4-88-801 is feasible to be gathered under the Arkansas All-Payer Claims Database, or "APCD," under the "Arkansas Healthcare Transparency Initiative Act," codified under Ark. Code Ann. §§ 23-61-901 et seq. PBMs and Healthcare insurers subject to this Section shall assist the Commissioner and APCD to determine whether the reporting information under Ark. Code Ann. § 4-88-803 is reasonably feasible to be gathered technologically and reported to APCD. In the absence of an APCD mechanism to gather and report this information, PBMs and Healthcare insurers, subject to this Section, shall file written reports in the format as required by the Department under Section 9(C)(2) of this Rule.

4. 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 § 23-61-207 and not subject to the Freedom of Information Act of 1967, under § 25-19-101 et seq. The confidentiality and exemption from the Freedom of Information Act of 1967, under this subdivision, shall also include any underlying records or data forming the basis of the report, which may be submitted to the Commissioner, or APCD.

5. 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.

Section 10. 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 § 5-55-111;

(2) Abuse or fraud as defined in § 20-77-1702; or

(3) Insurance fraud.

Section 11. Penalties

Violations of this Rule shall constitute an unfair or deceptive act under Ark. Code Ann. §23-66-206; therefore, the penalties, actions or orders, including but not limited to monetary fines, suspension, or revocation of license, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

Section 12 Provisions in Rule Applicable to All Healthcare Payors

Any language in the provisions of this Rule referring or referencing requirements of an insurer, healthcare insurer, or HMO shall include health benefit plans issued or delivered by a Healthcare Payor.

Section 13. Previously Issued Bulletins on MAC Law and NADAC Pricing Minimums

PBMs shall follow the standards announced by the Commissioner in AID Bulletins 11-2021, 13-2021 and 5-2022 for maximum allowable cost and National Average Drug Acquisition Cost ("NADAC") reimbursement processing. Violations of those standards shall be subject to the penalties and fines in this Rule.

Section 14. 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.

Section 15. Effective Date

This Rule shall be effective upon approval by the Arkansas Legislative Council as an Emergency Rule, and thereafter filing of a permanent rule ten (10) days after filing a final rule with the Secretary of State.

Alan McClain

ALAN MCCLAIN
INSURANCE COMMISSIONER

June 16, 2022

DATE