



Hugh McDonald
SECRETARY OF COMMERCE

Alan McClain
COMMISSIONER,
ARKANSAS INSURANCE
DEPARTMENT

MEMORANDUM

To: Alan McClain, Commissioner; Russ Galbraith, Chief Deputy Commissioner; Allison Hatfield, Department of Commerce Chief of Staff; Cole Jester, Deputy Legal Counsel, Arkansas Governor's Office

From: Booth Rand, AID General Counsel

Re: Executive Summary Describing Proposed Amendments to Rule 118

This memo pertains to AID's PBM Rule 118. Last spring, we received Governor's Office approval to issue out amendments to this Rule. The proposed rule amendments were filed, and we held a public hearing on April 10, 2024 to adopt the proposed amendments. During that same time period, we started receiving a significant number of pharmacy complaints related to PBMs reimbursement being higher to its affiliates than to independent pharmacies. This is a violation of our PBM statute in Ark. Code Ann. § 23-92-506(a)(4). In response to or in reaction to the complaints that not only AID has received on this issue but also the Governor's office, while we have this rule open, I am desiring to increase the fines for such infractions to \$5,000.00 per violation with no cap, from its earlier restriction to a \$50,000.00 cap. To avoid challenges to this new policy from PBMs, out of an abundance of caution, because it was not originally proposed in the draft AID amendments, I would like to re-notice this Rule again for comments with these increased fine amounts.

The rest of the amendments are simply updates to the Rule to conform to various PBM related Acts passed during the regular session of the 94th General Assembly.

1. Sections 3 and 4: Amendments to clarify AID jurisdiction

Act 302 of 2023 makes it clear that the General Assembly intends for AID's Pharmacy Benefits Managers Regulation Program to cover any pharmacy benefit manager ("PBM") within AID's jurisdiction administering pharmacy benefits for health benefit plans for all residents of this state and that it is the location of the resident, and not the PBM's payor, that determines jurisdiction. AID proposes changing the definition of "health benefit plans" to address this intent.

AID also proposes changing language limiting the definition of “health benefit plan” to recognize that federal law preempting state jurisdiction over Medicare plans may change, and if such changes enable state jurisdiction, AID intends to exercise jurisdiction over those plans to the extent permitted under federal law.

AID proposes modifying the exclusion of entities providing claims processing services or other prescription drug or device services for fee-for-service Arkansas Medicaid from the definition of “pharmacy benefits manager” to recognize that when the Arkansas Medicaid Program employs a PBM to maintain a Maximum Allowable Cost (“MAC”) List, the entity will be considered a PBM for purposes of Arkansas’s MAC law. See Ark. Code Ann. § 17-92-507(f).

2. Section 5: Licensure and Financial Requirements

Currently, one of the Standards of Review at 9(D) requires the Commissioner to deny the license of any PBM applicant operating in a financially hazardous condition. There is no definition of that condition and the standards applied to insurers are overly stringent for PBMs, which are passthroughs for insurers and do not accept risk in the manner of an insurer. For that reason, the Department proposes that this standard be replaced, and that licensure be denied if “[t]he 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.”

AID also proposes amending a second standard of review that prohibits licensure for any violation of Rule 118 or state law. AID proposes replacing this language so that denial would occur if “[t]he Commissioner determines that the magnitude of violation or non-compliance demonstrated by the PBM warrants denial of licensure.”

3. Section 8: Examinations of PBMs and Healthcare Payors

Act 994 of 2019 required PBMs to report aggregate rebate information on a quarterly basis to the Commissioner. Act 302 of 2023 struck that requirement but authorized the Commissioner to examine the books and records of a PBM to determine aggregate rebate information. This language is codified at Ark. Code Ann. § 23-92-505(b)(1) and (2) and is now repeated at (C)(2).

4. Section 9: Reporting Requirements

This section has been reorganized so that it now only includes information related to statutorily required reporting requirements. Because MAC reporting, formerly located at 9(A), is distinguishable from the other reports as it is only required upon request of the Commissioner, AID is striking that language and repeating it at new Section 10. Language at 9(B) relating to MAC appeals has been relocated to Section 11.

Renumbered 9(A) references a 2018 reporting requirement established at Ark. Code Ann. § 4-88-803(d), which requires PBMs providing services to plans funded by state dollars to submit information to determine whether the PBM is engaged in spread pricing. In 2019, the PBM Licensure Act was amended to prohibit spread pricing. This prohibition applies to PBMs serving self-funded health benefit plans, including governmental plans using state dollars. Because spread pricing is now prohibited but the reporting requirement remains in place, AID is proposing to simplify the reporting requirement to a certification by a PBM that it does not practice spread pricing.

New subdivisions 9(B) and 9(C) identify reporting requirements resulting from Act 965 of 2021, Arkansas Fairness in Cost Sharing Act, and Act 333 of 2023, Arkansas Pharmacy Benefits Manager Share the Savings Act.

5. New Sections 10 and 11: MAC Recordkeeping and MAC Appeals

Please see comments for Section 9.

6. New Section 13: Compliance with Bulletins

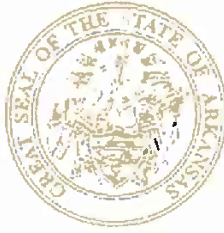
The current Section 13 addresses compliance with specific bulletins and is not an exhaustive list of all bulletins regulating PBMs. To avoid confusion, the new language at Section 13 advises PBMs to reasonably strive to comply with these bulletin standards as announced by the Commissioner.

7. Section 14: Penalties

Prior to Act 302 of 2023, the General Assembly authorized the Department to establish penalties for violations of the PBM Licensure Act and did not specify the maximum amounts for those penalties. The Department promulgated Rule 118 and included a penalty structure. These penalties were not capped and ranged from up to ten thousand dollars (\$10,000) to twenty-five thousand dollars (\$25,000) per penalty. Because there was no statutory support for those penalties, the Department enforced MAC pricing violations using the penalties within the Trade Practices Act, Ark. Code Ann. § 23-66-201 et seq., ten thousand dollars (\$10,000) per violation not to exceed fifty thousand dollars (\$50,000) within a six-month period. The Department enforced National Average Drug Acquisition Cost ("NADAC") violations using AID's general penalty statute at Ark. Code Ann. § 23-60-108, which provides for a one thousand dollars (\$1,000) penalty, not to exceed fifty thousand dollars (\$50,000) in any six-month period.

Act 302 of 2023 revised the existing PBM licensure penalty structure to impose a penalty up to five thousand dollars (\$5,000) per violation of specific MAC and NADAC drug pricing standards without limitation. It also established that the Commissioner could revoke or suspend the license of a PBM that has committed a pattern of violations or has failed to follow specific MAC and NADAC standards.

The Department proposes to change its penalties in this Rule for MAC and NADAC violations to comply with Act 302 of 2023. In addition, AID proposes to apply the same penalty amounts to violations of the affiliate payment restrictions in Ark. Code Ann. § 23-92-506(a)(4) to \$5,000.00 per violation with no cap.



**STATE OF ARKANSAS
SARAH HUCKABEE SANDERS
GOVERNOR**

Request for Governor's Approval of Proposed Rule or Regulation

Department /Agency: Arkansas Insurance Department (AID)

Short Title of Rule: AID Rule 118: Pharmacy Benefits Managers Regulation

New Rule: ☐ Yes ☒ No

Amendment to Existing Rule: ☒ Yes ☐ No

State Mandate: ☒ Yes ☐ No

Federal Mandate: ☐ Yes ☒ No

If yes, please provide the legal citation of the mandate: Ark. Code. Ann. § 23-92-509

Legal Authority for Rule: Ark. Code Ann. § 23-92-509

Proposed Effective Date: 11/4/2024

Emergency Rule: ☐ Yes ☒ No

Expedited Rule Requested: ☐ Yes ☐ No

Summary of Proposed New Rule or Proposed Amendment to Existing Rule:

Proposed amendments include updating language to comply with acts passed during the regular session of the 94th General Assembly. Some updates address needs from comments from its last public hearing as well as other matters since this was last filed. Please see attached Executive Summary for more details.

Financial Impact: ☐ Yes ☒ No ☐ Unknown; If yes or unknown, please explain:

Public Hearing Occurred on Rule: ☒ Yes ☐ No

Controversial: ☐ Yes ☒ No

If yes, please explain and provide detail of expected opposition.

We do not anticipate this proposed Rule to be controversial; however, we will update ADOC and Governor's Office in the event of opposition.

Two Rules Repealed: ☐

Exception from the Governor: ☒

First Rule Repealed:

Brief explanation of why repeal is appropriate:

Second Rule Repealed:

Brief explanation of why repeal is appropriate:

Documents Required for Approval Process

Please note that the Governor's office will not begin the approval process if any of the following applicable documents are not enclosed with the approval request.

- ☐ BLR Questionnaire
- ☐ BLR Financial Impact Statement
- ☐ Proposed Rule - clean version
- ☐ Mark-Up of Rule, if amended from previous version
- ☐ Copy of Act or Regulation, if Rule is pursuant to State or Federal mandate

Contact Information

Department POC for Rules Process: Booth Rand, General Counsel, booth.rand@arkansas.gov

Department POC for this Rule: Booth Rand, General Counsel, booth.rand@arkansas.gov

NOTE: All documents must be returned to the Governor's Counsel as a single PDF file.

Questionnaire for filing Proposed Rules with ALC

**QUESTIONNAIRE FOR FILING PROPOSED RULES WITH
THE ARKANSAS LEGISLATIVE COUNCIL**

DEPARTMENT Arkansas Insurance Department (AID)
BOARD/COMMISSION _____
BOARD/COMMISSION DIRECTOR Alan McClain, Insurance Commissioner
CONTACT PERSON Booth Rand, General Counsel, AID
ADDRESS One Commerce Way, Suite 102, Little Rock, AR 72202
PHONE NO. (501) 371-2827 **EMAIL** booth.rand@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
Booth Rand
PRESENTER EMAIL(S) booth.rand@arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

1. What is the official title of this rule?
AID Rule 118: Pharmacy Benefits Managers Regulation
2. What is the subject of the proposed rule? Amendments to our PBM Rule 118
3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☒

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☒ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☒

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire? _____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☐ No ☒

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes ☒ No ☐

If yes, please provide the state statute and/or rule citation.

Ark. Code Ann. § 23-92-509

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☒

If yes, please list the rules being repealed.

If no, please explain.

No, we are requesting an exemption from the portion of Executive Order 23-02 that requires agencies to simultaneously submit two rules for repeal for every one rule presented for rulemaking. This rule will not increase the number of rules enforced by AID, and AID does not have two rules to repeal.

8. Is this a new rule? Yes ☐ No ☒

Does this repeal an existing rule? Yes ☐ No ☒

If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☒ No ☐

If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Ark. Code Ann. § 23-92-509 sets out both discretionary and mandatory authorities for promulgation of PBM rules. Subdivision (a) provides a listing of rules that the Commissioner may adopt whereas subdivisions (b)(1) and (2) require the Commissioner to adopt rules related to penalties and pharmacy network adequacy.

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☒ No ☐

If yes, please provide the year of the act(s) and act number(s).

Act 302 of 2023

Act 333 of 2023

Act 965 of 2021

11. What is the reason for this proposed rule? Why is it necessary?

Because AID already has an existing rule in this matter, the rule should be updated to reflect recent legislative acts affecting PBMS, especially the portions of those acts that require rulemaking, as well as to adopt new policy changes occurring after our last hearing related to this proposed rule.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

<https://www.insurance.arkansas.gov/industry-regulation/legal/proposed-rules/>

13. Will a public hearing be held on this proposed rule? Yes ☒ No ☐

If yes, please complete the following:

Date: 09/10/2024

Time: 10:00 am

Place: Arkansas Insurance Department

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. 10/10/2024

15. What is the proposed effective date for this rule? 1/01/2025

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

Arkansas Pharmacists Association, Individual Arkansas pharmacists, and Pharmaceutical Care Management Association

19. Is the rule expected to be controversial? Yes ☐ No ☒

If yes, please explain.

Although we do not expect the rule to be controversial, we cannot state with any certainty that it will be noncontroversial.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Insurance Department (AID)

BOARD/COMMISSION _____

PERSON COMPLETING THIS STATEMENT Booth Rand, General Counsel, AID

TELEPHONE NO. (501) 371-2827 **EMAIL** booth.rand@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE AID 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 no, please explain:

(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 reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

(d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

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?

Current Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

Next Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

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

Current Fiscal Year

General Revenue ⁰ _____
 Federal Funds ⁰ _____
 Cash Funds ⁰ _____
 Special Revenue ⁰ _____
 Other (Identify) ⁰ _____
 Total \$ 0.00 _____

Next Fiscal Year

General Revenue ⁰ _____
 Federal Funds ⁰ _____
 Cash Funds ⁰ _____
 Special Revenue ⁰ _____
 Other (Identify) ⁰ _____
 Total \$ 0.00 _____

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

Current Fiscal Year

\$ _____

Next Fiscal Year

\$ _____

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

Current Fiscal Year

\$ 0.00 _____

Next Fiscal Year

\$ 0.00 _____

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?

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.

Clean Rule 118

**PROPOSED AMENDED
RULE 118 PHARMACY BENEFITS MANAGERS REGULATION**

- 1. AUTHORITY**
- 2. PURPOSE**
- 3. APPLICABILITY & SCOPE**
- 4. DEFINITIONS**
- 5. LICENSURE & FINANCIAL REQUIREMENTS**
- 6. CONTRACT REVIEW**
- 7. PHARMACY NETWORK ADEQUACY AND COMPENSATION**
- 8. EXAMINATIONS OF PBMS AND HEALTHCARE PAYORS**
- 9. REPORTING REQUIREMENTS**
- 10. MAC RECORDKEEPING REQUIREMENTS**
- 11. MAC APPEALS**
- 12. PHARMACY AUDIT BILL OF RIGHTS**
- 13. COMPLIANCE WITH BULLETINS**
- 14. PENALTIES**
- 15. PROVISIONS IN RULE APPLICABLE TO ALL HEALTHCARE PAYORS**
- 16. SEVERABILITY**

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, 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 unless the Arkansas Medicaid Program employs a PBM to maintain a Maximum Allowable Cost List, in which case, this entity shall be considered a PBM for purposes of Ark. Code Ann. § 17-92-507.

(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:

(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

(A) Pharmacy Network Adequacy.

(1) In order to effectively implement Ark. Code Ann. § 23-92-505, because a PBM is actually administering 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.

(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

(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

(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, 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

(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
INSURANCE COMMISSIONER

DATE

Markup Rule 118

PROPOSED AMENDED
RULE 118 PHARMACY BENEFITS MANAGERS REGULATION

1. AUTHORITY
2. PURPOSE
3. APPLICABILITY & SCOPE
4. DEFINITIONS
5. LICENSURE & FINANCIAL REQUIREMENTS
6. CONTRACT REVIEW
7. PHARMACY NETWORK ADEQUACY **AND COMPENSATION**
8. EXAMINATIONS **OF PBMS AND HEALTHCARE PAYORS**
9. REPORTING REQUIREMENTS
10. **MAC RECORDKEEPING REQUIREMENTS**
11. **MAC APPEALS**
12. PHARMACY AUDIT BILL OF RIGHTS
13. **COMPLIANCE WITH BULLETINS**
14. PENALTIES
15. PROVISIONS IN RULE APPLICABLE TO ALL HEALTHCARE PAYORS
16. ~~PREVIOUSLY ISSUED BULLETINS~~
16. SEVERABILITY
17. ~~EFFECTIVE DATE~~

Section 1. Authority

(A) This rule is issued pursuant to Ark. Code Ann. § 23-61-108(a)(1), § 17-92-507, and § ~~23-92-504(b)(1)~~ 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 ~~pharmacy benefits managers~~ 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 ~~as delineated in Ark. Code Ann. § 23-92-509 of pharmacy benefits managers~~ 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 ~~pharmacy benefit managers~~ PBMs 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 benefits managers~~ 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 ~~in~~ 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)(B)(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;

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

(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~~ 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, 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 ~~Pharmacy benefits manager~~ PBM charges the Health benefit plan the amount it actually pays a ~~pharmacy 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 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 ~~pharmacy benefits manager~~ 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 ~~pharmacy benefits manager~~ 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 unless the Arkansas Medicaid Program employs a PBM to maintain a Maximum Allowable Cost List, in which case, this entity shall be considered a PBM for purposes of Ark. Code Ann. § 17-92-507.

(15) ~~"Pharmacy benefits manager 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) ~~"Pharmacy benefits manager 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 ~~pharmacy benefits managers 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 ~~pharmacy benefits manager 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. ~~and~~

(20) "Third party" means a person, business, or entity other than a ~~pharmacy benefits manager 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 ~~Pharmacy benefits manager PBM~~ charges a Health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the ~~Pharmacy benefits manager PBM~~ pays the pharmacy. Pharmacist.

Section 5. Licensure & Financial Requirements

(A) Initial License and Renewal. A ~~PBM~~ 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) 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;~~

(3) Contact information, including name, title, mailing address, email address, and direct phone number, for the following individuals:

_____ (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 ~~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~~ 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 ~~PBM's~~ applicant's standard, generic contract template, provider manual or other appropriate items incorporated by reference which it uses for contracts entered into by the ~~PBM~~ 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 ~~PBM's~~ 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 applicant in this State to be serviced on an annual basis for all Healthcare insurers with whom the ~~PBM applicant~~ has contracted, and, if applicable, the population or numbers of enrollees administered by the PBM 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 PBM applicant has compliant processes established to adhere to all of the requirements in Ark. Code Ann. § 17-92-507, concerning ~~Maximum Allowable Cost~~ 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 PBM 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 ~~PBM's~~ applicant's network's service areas by county in this State for a Healthcare insurer and the ~~PBM's~~ 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 Process of Initial Licensure Applications.

~~(1) For initial licensure applications, upon~~ Upon receipt of a complete application for items required under Section (5)(A) of this Rule, the Commissioner shall review the application and:

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

~~(b)(2)~~ (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

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

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

~~(ii)(b)~~ (ii)(b) 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)(C) Renewal.

(1) A PBM license shall be renewed annually. A renewal application shall require ~~proof~~ 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 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: 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:

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

(ii)(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)(D)(1) Standards of Review. The Commissioner shall deny an initial application for licensure or deny renewal by of a PBM license 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~~ 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 PBM has been determined by the Commissioner to be in violation or noncompliance with the requirements in this Rule or Arkansas state law~~ 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)(1)(b) (5)(B)(2) or has failed to submit a renewal application and information under Section 5(B)(2) (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 Section 5(B)(3)(a) or (e) (5)(D)(1) of this Rule.

(4)(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.

(C)(F) Confidentiality. The information submitted by a PBM under Section 5(A)(6) through (16) (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], 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(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

(A) Pharmacy Network Adequacy.

(1) In order to effectively implement Ark. Code Ann. § 23-92-505, because a PBM is actually administering 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.

~~For Healthcare insurers using PBMs~~ A Healthcare insurer using a PBM 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)(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) For Healthcare insurers Payors using PBMs~~ A Healthcare insurer or Payor using a PBM for administration of pharmacy benefits ~~of its Health benefit plans, the Healthcare insurers~~ 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. ~~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.~~

(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 ~~in~~ to which a PBM has adjusted a pharmacist's or pharmacy's reimbursement

pricing ~~has been adjusted~~, on the average on a quarterly basis, ~~inventory costs under 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 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) Compensation or Reimbursement Requirements Regardless of Network Adequacy.

1. Pursuant to Ark. Code Ann. §§ 23-92-506(b)(4) and 17-92-507, ~~in no event, however, shall a PBM shall not~~ reimburse a pharmacy or pharmacist in the state in an amount less than the amount that the ~~pharmacy benefits manager~~ PBM reimburses a ~~pharmacy benefits manager~~ 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.

(A) ~~Examinations of PBMs and Healthcare Payors.~~ 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

~~(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(e)(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(e)(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)~~ (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: ~~(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) 23-61-1003(10); 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.~~

(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.

~~(4) (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. 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) (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

(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 statistical 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, 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 ~~10~~ 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. Violations of these standards shall be subject to the penalties and fines within this Rule.

Section 11. 14. Penalties

~~The following penalties or fines shall apply to violations of Maximum Allowable Cost law in Ark. Code Ann. §17-92-507 or to violations of Ark. Code Ann. §23-92-506.~~

~~—(1) For unintentional violations, the fines or penalties shall be up to \$15,000 per violation;~~

~~_____ (2) For violations in which the company knew or should have known the conduct is a violation, the penalties shall be up to \$25,000 per violation, with no total limitation on the aggregate amount of penalties;~~

~~_____ (3) For other violations either of the PBM Licensure Act or any Section of this Rule, the penalty shall be \$10,000 per violation;~~

~~_____ (a) Upon finding of multiple violations, or a practice or pattern of violations, the Commissioner may additionally: revoke or suspend the license of a PBM;~~

~~_____ (b) apply the penalties or actions authorized to the Commissioner under Ark. Code Ann. §23-66-209 and 210.~~

(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 ~~12~~ 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 ~~HMO~~ 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 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 these standards shall be subject to the penalties and fines in this Rule.~~

Section ~~14~~ 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.

~~**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
INSURANCE COMMISSIONER

DATE

ACT 302 of 2023

1 State of Arkansas

As Engrossed: S2/9/23

2 94th General Assembly

A Bill

3 Regular Session, 2023

SENATE BILL 94

5 By: Senator K. Hammer

6 By: Representative Achor

For An Act To Be Entitled

9 AN ACT TO MODIFY THE ARKANSAS PHARMACY BENEFITS
10 MANAGER LICENSURE ACT; TO AMEND THE DEFINITION OF
11 "HEALTH BENEFIT PLAN" UNDER THE ARKANSAS PHARMACY
12 BENEFITS MANAGER LICENSURE ACT; TO REPEAL THE
13 REQUIREMENT FOR QUARTERLY REPORTS BY A PHARMACY
14 BENEFITS MANAGER; TO CLARIFY THE AUTHORITY OF THE
15 INSURANCE COMMISSIONER UNDER THE ARKANSAS PHARMACY
16 BENEFITS MANAGER LICENSURE ACT; AND FOR OTHER
17 PURPOSES.

Subtitle

21 TO MODIFY THE ARKANSAS PHARMACY BENEFITS
22 MANAGER LICENSURE ACT.

25 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

27 SECTION 1. Arkansas Code § 23-92-503(2), concerning the definition of
28 "health benefit plan" used in the Arkansas Pharmacy Benefits Manager
29 Licensure Act, is amended to read as follows:

30 (2)(A) "Health benefit plan" means any individual, blanket, or
31 group plan, policy, or contract for healthcare services issued or delivered
32 by a healthcare payor ~~in~~ to residents of this state.

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

34 (i) Accident-only plans;

35 (ii) Specified disease plans;

36 (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 or 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.

(C) "Health benefit plan" includes any group plan, policy, or contract for healthcare services issued outside this state that provides benefits to residents of this state;

SECTION 2. Arkansas Code § 23-92-504(b), concerning the rule-making authority of the Insurance Commissioner, is amended to read as follows:

(b)(1) The commissioner shall issue rules establishing the licensing, fees, application, financial standards, penalties, compliance and enforcement requirements, and reporting requirements of pharmacy benefits managers under this subchapter.

~~(2)(A) When adopting the initial rules to implement this subchapter, the final rule shall be filed with the Secretary of State for adoption under § 25-15-204(f).~~

~~(i) On or before September 1, 2018, or~~

~~(ii) If approval under § 10-3-309 has not occurred by September 1, 2018, as soon as practicable after approval under § 10-3-309.~~

~~(B) The State Insurance Department shall file the proposed rule with the Legislative Council under § 10-3-309(c) sufficiently in advance of September 1, 2018, so that the Legislative Council may consider the rule for approval before September 1, 2018.~~

SECTION 3. Arkansas Code § 23-92-505(b), concerning the requirement for quarterly reports by a pharmacy benefits manager to the Insurance Commissioner, is amended to read as follows:

(b)(1) ~~A pharmacy benefits manager shall report to the Insurance Commissioner on a quarterly basis for each healthcare payor the following information:~~

~~(A) The aggregate amount of rebates received by the pharmacy benefits manager;~~

~~(B) The aggregate amount of rebates distributed to the appropriate healthcare payor;~~

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

~~(D) The individual and aggregate amount paid by the healthcare payor to the pharmacy benefits manager for pharmacist services itemized by pharmacy, by product, and by goods and services; and~~

~~(E) The individual and aggregate amount a pharmacy benefits manager paid for pharmacist services itemized by pharmacy, by product, and by goods and services~~ The Insurance Commissioner may examine the books and records of a pharmacy benefits manager as necessary to determine:

(A) The aggregate amount of rebates received by a pharmacy benefits manager;

(B) The aggregate amount of rebates distributed by a pharmacy benefits manager to an appropriate healthcare payor; and

(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.

~~(2) The report required under subdivision (b)(1) of this section is:~~

~~(A) Proprietary and confidential under § 23-61-107(a)(4) and § 23-61-207; and~~

~~(B) Not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq~~ The commissioner may examine the books and records of a pharmacy benefits manager as necessary to determine:

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

(B) The individual and aggregate amount a pharmacy benefits manager paid for pharmacist services itemized by pharmacy, product,

1 and goods and services, including other prescription drug or device services.

2

3 SECTION 4. Arkansas Code § 23-92-505, concerning the network adequacy
4 of pharmacy benefits managers under the Arkansas Pharmacy Benefits Manager
5 Licensure Act, is amended to add an additional subsection to read as follows:

6 (d) This section does not limit the power of the commissioner to
7 examine or audit the books and records of a pharmacy benefits manager under
8 this subchapter.

9

10 SECTION 5. Arkansas Code § 23-92-508 is amended to read as follows:
11 23-92-508. Enforcement.

12 (a) The Insurance Commissioner shall enforce this subchapter.

13 (b)(1) The commissioner may examine or audit the books and records of
14 a pharmacy benefits manager providing claims processing services or other
15 prescription drug or device services for a health benefit plan to determine
16 if the pharmacy benefits manager is in compliance with this subchapter.

17 (2) The information or data acquired during an examination under
18 subdivision (b)(1) of this section is:

19 (A) Considered proprietary and confidential under § 23-61-
20 107(a)(4) and § 23-61-207; and

21 (B) Not subject to the Freedom of Information Act of 1967,
22 § 25-19-101 et seq.

23 (c) After notice and opportunity for hearing, the commissioner may:

24 (1) Impose a penalty of up to five thousand dollars (\$5,000) per
25 violation against a pharmacy benefits manager if the commissioner finds that
26 the pharmacy benefits manager has not:

27 (A) Followed the process established for determining
28 pricing or costs under the Maximum Allowable Cost List under § 17-92-507; or

29 (B) Used the national average drug acquisition cost under
30 § 23-92-506(b); or

31 (2) Revoke or suspend the license of a pharmacy benefits manager
32 if the commissioner finds that the pharmacy benefits manager:

33 (A) Has committed a pattern of violations of this
34 subchapter;

35 (B) Has not followed the process established for
36 determining pricing and costs under the Maximum Allowable Cost List under §

1 17-92-507; or

2 (C) Has not used the national average drug acquisition
3 cost under § 23-92-506(b).

4
5 SECTION 6. Arkansas Code § 23-92-510, concerning the applicability of
6 the Arkansas Pharmacy Benefits Manager Licensure Act, is amended to add an
7 additional subsection to read as follows:

8 (d) This subchapter applies to a health benefit plan that is issued
9 outside this state if that health benefit plan provides benefits for
10 healthcare services to residents of this state.

11
12 */s/K. Hammer*

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15 **APPROVED: 3/16/23**
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ACT 333 of 2023

1 State of Arkansas
2 94th General Assembly
3 Regular Session, 2023
4

A Bill

HOUSE BILL 1481

5 By: Representative Achor
6 By: Senator J. Boyd
7

For An Act To Be Entitled

8
9 AN ACT TO CREATE THE HEALTHCARE INSURER SHARE THE
10 SAVINGS ACT; TO CREATE THE ARKANSAS PHARMACY BENEFITS
11 MANAGER SHARE THE SAVINGS ACT; AND FOR OTHER
12 PURPOSES.
13

Subtitle

14
15 TO CREATE THE HEALTHCARE INSURER SHARE
16 THE SAVINGS ACT; AND TO CREATE THE
17 ARKANSAS PHARMACY BENEFITS MANAGER SHARE
18 THE SAVINGS ACT.
19
20
21

22 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
23

24 SECTION 1. Arkansas Code Title 23, Chapter 79, is amended to add an
25 additional subchapter to read as follows:
26

27 Subchapter 24 – Healthcare Insurer Share the Savings Act
28

29 23-79-2401. Title.

30 This subchapter shall be known and may be cited as the "Healthcare
31 Insurer Share the Savings Act".
32

33 23-79-2402. Definitions.

34 As used in this subchapter:

35 (1) "Defined cost sharing" means a deductible payment or
36 coinsurance amount imposed on an enrollee for a covered prescription drug



1 under the enrollee's health benefit plan;

2 (2) "Enrollee" means an individual entitled to coverage of
 3 healthcare services from a healthcare insurer;

4 (3)(A) "Health benefit plan" means any individual, blanket, or
 5 group plan, policy, or contract for healthcare services issued or delivered
 6 by a healthcare insurer in this state.

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

8 (i) Accident-only plans;

9 (ii) Specified disease plans;

10 (iii) Disability income plans;

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

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

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

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

21 (viii) Any state or local governmental employee
 22 plan;

23 (4)(A) "Healthcare insurer" means a:

24 (i) Health insurance issuer that:

25 (a) Is subject to state law regulating
 26 insurance; and

27 (b) Offers health insurance coverage under 42
 28 U.S.C. § 300gg-91, as it existed on January 1, 2023;

29 (ii) Health maintenance organization; or

30 (iii) Hospital and medical service corporation.

31 (B) "Healthcare insurer" does not include an entity that
 32 provides only dental benefits or eye and vision care benefits;

33 (5) "Price protection rebate" means a negotiated price
 34 concession that accrues directly or indirectly to a healthcare insurer, or
 35 other party on behalf of the healthcare insurer, if there is an increase in
 36 the wholesale acquisition cost of a prescription drug above a specified

1 threshold; and

2 (6) "Rebate" means:

3 (A) A negotiated price concession, including without
 4 limitation base price concessions, whether described as a rebate or not,
 5 reasonable estimates of any price protection rebates, and performance-based
 6 price concessions that may accrue, directly or indirectly, to the healthcare
 7 insurer during the coverage year from a manufacturer or other party in
 8 connection with the dispensing or administration of a prescription drug; and

9 (B) Any reasonable estimate of a negotiated price
 10 concession, fee, and other administrative cost that is passed through, or is
 11 reasonably anticipated to be passed through, to the healthcare insurer and
 12 serves to reduce the healthcare insurer's liabilities for a prescription
 13 drug.

14
 15 23-79-2403. Implementation of subchapter -- Requirements.

16 (a) An enrollee's defined cost sharing for a prescription drug shall
 17 be calculated at the point-of-sale based on a price that is reduced by an
 18 amount equal to at least one hundred percent (100%) of all rebates received,
 19 or to be received, in connection with the dispensing or administration of the
 20 prescription drug.

21 (b) This subchapter shall not preclude a healthcare insurer from
 22 decreasing an enrollee's defined cost sharing by an amount greater than that
 23 required under subsection (a) of this section.

24 (c) In implementing the requirements of this section, the state shall
 25 only regulate a healthcare insurer to the extent permissible under applicable
 26 law.

27 (d)(1) In complying with this section, a healthcare insurer or its
 28 agents shall not publish or otherwise reveal information regarding the actual
 29 amount of rebates a healthcare insurer receives on a product or therapeutic
 30 class of products, manufacturer, or pharmacy-specific basis.

31 (2) The information described in subdivision (d)(1) of this
 32 section is:

33 (A) Protected as a trade secret;

34 (B) Considered proprietary and confidential under § 23-61-
 35 107(a)(4) and § 23-61-207;

36 (C) Not subject to disclosure under the Freedom of

1 Information Act of 1967, § 25-19-101 et seq.; and

2 (D) Not to be disclosed:

3 (i) Directly or indirectly; or

4 (ii) In a manner that would:

5 (a) Allow for the identification of an
6 individual product, therapeutic class of products, or manufacturer; or

7 (b) Have the potential to compromise the
8 financial, competitive, or proprietary nature of the information.

9 (3) A healthcare insurer shall impose the confidentiality
10 protections of this section on any vendor or downstream third party that
11 performs healthcare or administrative services on behalf of the healthcare
12 insurer that may receive or have access to rebate information.

13
14 SECTION 2. Arkansas Code Title 23, Chapter 92, is amended to add an
15 additional subchapter to read as follows:

16
17 Subchapter 7 – Arkansas Pharmacy Benefits Manager Share the Savings Act

18
19 23-92-701. Title.

20 This subchapter shall be known and may be cited as the "Arkansas
21 Pharmacy Benefits Manager Share the Savings Act".

22
23 23-92-702. Purpose.

24 The purpose of this subchapter is to require pharmacy benefits managers
25 to share the benefit of rebates with enrollees in this state.

26
27 23-92-703. Definitions.

28 As used in this subchapter:

29 (1) "Defined cost sharing" means a deductible payment or
30 coinsurance amount imposed on an enrollee for a covered prescription drug
31 under the enrollee's health benefit plan;

32 (2) "Enrollee" means an individual entitled to coverage of
33 healthcare services from a healthcare insurer;

34 (3)(A) "Health benefit plan" means any individual, blanket, or
35 group plan, policy, or contract for healthcare services issued or delivered
36 by a healthcare insurer in this state.

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

2 (i) Accident-only plans;

3 (ii) Specified disease plans;

4 (iii) Disability income plans;

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

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

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

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

15 (viii) Any state or local governmental employee
16 plan;

17 (4) "Healthcare insurer" means an insurance company that is
18 subject to state law regulating insurance including without limitation a
19 health maintenance organization or a hospital and medical service
20 corporation;

21 (5) "Pharmacy benefits management service" means a service to:

22 (A) Negotiate the price of prescription drugs, including
23 negotiating and contracting for direct or indirect rebates, discounts, or
24 other price concessions;

25 (B) Manage any aspect of a prescription drug benefit,
26 including without limitation:

27 (i) Claims processing services;

28 (ii) The performance of drug utilization review;

29 (iii) The processing of drug prior authorization
30 requests;

31 (iv) The adjudication of appeals or grievances
32 related to a prescription drug benefit;

33 (v) Controlling the cost of covered prescription
34 drugs; or

35 (vi) The provision of services related to the
36 services described under this subdivision (5)(B);

(C) Disburse or distribute rebates, manage or participate in incentive programs or arrangements for pharmacist services, negotiate or enter into contractual arrangements with pharmacists or pharmacies, or both, develop formularies, or employ advertising or promotional services;

(D) Perform any other administrative, managerial, clinical, pricing, financial, reimbursement, or billing service; and

(E) Perform any other services as the Insurance Commissioner may include by rule;

(6)(A) "Pharmacy benefits manager" means a person, business, or entity that, pursuant to a written agreement with a healthcare insurer or health benefit plan, either directly or indirectly provides one (1) or more pharmacy benefits management services on behalf of the healthcare insurer or health benefit plan, and any agent, contractor, intermediary, affiliate, subsidiary, or related entity of the person, business, or entity that facilitates, provides, directs, or oversees the provision of the pharmacy benefits management service or services.

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

(i) Healthcare facility licensed in Arkansas;

(ii) Healthcare professional licensed in Arkansas;

or

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

(7) "Price protection rebate" means a negotiated price concession that accrues directly or indirectly to a healthcare insurer, or other party on behalf of the healthcare insurer, if there is an increase in the wholesale acquisition cost of a prescription drug above a specified threshold; and

(8) "Rebate" means:

(A) A negotiated price concession including without limitation base price concessions, whether described as a rebate or not, reasonable estimates of any price protection rebates, and performance-based price concessions that may accrue, directly or indirectly, to the healthcare insurer during the coverage year from a manufacturer or other party in connection with the dispensing or administration of a prescription drug; and

(B) Any reasonable estimate of a negotiated price concession, fee, and other administrative cost that is passed through, or is

1 reasonably anticipated to be passed through, to the healthcare insurer and
2 serves to reduce the healthcare insurer's liabilities for a prescription
3 drug.

4
5 23-92-704. Implementation of subchapter – Requirements.

6 (a) An enrollee's defined cost sharing for a prescription drug shall
7 be calculated at the point-of-sale based on a price that is reduced by an
8 amount equal to at least one hundred percent (100%) of all rebates received,
9 or to be received, in connection with the dispensing or administration of the
10 prescription drug.

11 (b) This subchapter shall not preclude a pharmacy benefits manager
12 from decreasing an enrollee's defined cost sharing by an amount greater than
13 that required under subsection (a) of this section.

14 (c)(1) A pharmacy benefits manager shall submit a certification to the
15 Insurance Commissioner by January 1 of each calendar year certifying that the
16 pharmacy benefits manager has complied with the requirements of this section
17 during the previous calendar year.

18 (2) The certification under subdivision (c)(1) of this section
19 shall be signed by the chief executive officer or chief financial officer of
20 the pharmacy benefits manager.

21 (3) The form of the certification shall:

22 (A) Be in a format approved or established by the
23 commissioner; and

24 (B) Include the pharmacy benefits manager's best estimate
25 of the aggregate amount of rebates used to reduce enrollee-defined cost
26 sharing for prescription drugs in the previous calendar year based on
27 information known to the pharmacy benefits manager as of the date of the
28 certification.

29 (d)(1) In complying with this section, a pharmacy benefits manager or
30 its agents shall not publish or otherwise reveal information regarding the
31 actual amount of rebates a pharmacy benefits manager receives on a product or
32 therapeutic class of products, manufacturer, or pharmacy-specific basis.

33 (2) The information described in subdivision (d)(1) of this
34 section is:

35 (A) Protected as a trade secret;

36 (B) Considered proprietary and confidential under § 23-61-

1 107(a)(4) and § 23-61-207;

2 (C) Not subject to disclosure under the Freedom of
3 Information Act of 1967, § 25-19-101 et seq.; and

4 (D) Not to be disclosed:

5 (i) Directly or indirectly; or

6 (ii) In a manner that would:

7 (a) Allow for the identification of an
8 individual product, therapeutic class of products, or manufacturer; or

9 (b) Have the potential to compromise the
10 financial, competitive, or proprietary nature of the information.

11 (3) A pharmacy benefits manager shall impose the confidentiality
12 protections of this section on any vendor or downstream third party that
13 performs healthcare services or administrative services on behalf of the
14 pharmacy benefits manager that may receive or have access to rebate
15 information.

16
17 SECTION 3. DO NOT CODIFY. Severability.

18 (a) In implementing this act, the state shall regulate a health
19 benefit plan, healthcare insurer, or pharmacy benefits manager only to the
20 extent permissible under applicable law.

21 (b)(1) The provisions of this act are severable.

22 (2) The invalidity of any provision of this act shall not affect
23 other provisions of this act that can be given effect without the invalid
24 provision.

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26
27 APPROVED: 3/21/23
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36

ACT 965 of 2021

State of Arkansas As Engrossed: H3/4/21 H3/15/21 S4/13/21

93rd General Assembly

A Bill

Regular Session, 2021

HOUSE BILL 1569

By: Representatives Lundstrum, Barker, Boyd, Bragg, Brown, C. Cooper, Evans, Furman, D. Garner,
Gazaway, Haak, Hawks, Lowery, Maddox, Murdock, Penzo, Pilkington, Ray, Scott, S. Smith, Watson, D.
Whitaker, Wing, Wooten, C. Fite, V. Flowers, McCullough, Rye
By: Senators Rapert, L. Chesterfield, Gilmore, M. Johnson, Teague, T. Garner

For An Act To Be Entitled

AN ACT TO ESTABLISH THE ARKANSAS FAIRNESS IN COST
SHARING ACT; AND FOR OTHER PURPOSES.

Subtitle

TO ESTABLISH THE ARKANSAS FAIRNESS IN
COST SHARING ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. TEMPORARY LANGUAGE. DO NOT CODIFY. Legislative findings
and intent.

(a) The General Assembly finds that:

(1) Arkansans frequently rely on state-regulated commercial
insurers to secure access to the prescription drugs needed to protect their
health;

(2) Commercial insurance designs increasingly require a patient
to bear significant out-of-pocket costs for the patient's prescription drugs;

(3) High out-of-pocket costs on prescription drugs affect the
ability of patients to start new and necessary prescription drugs and to
adhere to their current prescription drugs regimen;

(4) High or unpredictable cost-sharing requirements are a main
driver of elevated out-of-pocket costs for patients and allow insurers to
capture and divert rebates, discounts, and price concessions that are
intended to benefit patients at the pharmacy counter;



1 (5) Insurers unfairly increase cost-sharing burdens on patients
2 by refusing to count third-party assistance toward a patient's cost-sharing
3 contributions;

4 (6) The burdens of high or unpredictable cost-sharing
5 requirements are borne disproportionately by patients with chronic or
6 debilitating medical conditions;

7 (7) It is necessary to restrict the ability of insurers and
8 their intermediaries to use unfair cost-sharing design to retain rebates,
9 discounts, and price concessions that instead should be directly passed on to
10 patients as cost savings at the point of sale of prescription drugs; and

11 (8) Patients need equitable and accessible health coverage that
12 does not impose unfair cost-sharing burdens upon them.

13 (b) It is the intent of the General Assembly to ensure that a state-
14 regulated insurer and the entities that contract with the state-regulated
15 insurer do not restrict patient access to prescription drugs by refusing to
16 count third-party cost-sharing assistance toward a patient's cost-sharing
17 obligations, a practice that is detrimental to the consumer.

18
19 SECTION 2. Arkansas Code Title 23, Chapter 79, is amended to add an
20 additional subchapter to read as follows:

21 Subchapter 21 – Arkansas Fairness in Cost Sharing Act

22
23 23-79-2101. Title.

24 This subchapter shall be known and may be cited as the "Arkansas
25 Fairness in Cost Sharing Act".

26
27 23-79-2102. Definitions.

28 As used in this subchapter:

29 (1) "Cost-sharing requirement" means a copayment, coinsurance,
30 deductible, or annual limitation on cost sharing, including without
31 limitation a limitation subject to the Patient Protection and Affordable Care
32 Act, Pub. L. No. 111-148, that is required by or on behalf of an enrollee in
33 order to receive a specific healthcare service, including a prescription
34 drug, covered by a health benefit plan;

35 (2) "Enrollee" means an individual entitled to healthcare
36 services from a healthcare insurer;

1 (3)(A) "Health benefit plan" means any individual, blanket, or
2 group plan, policy, or contract for healthcare services issued or delivered
3 by a healthcare insurer in this state.

4 (B) "Health benefit plan" does not include:
5 (i) Accident-only plans;
6 (ii) Specified disease plans;
7 (iii) Disability income plans;
8 (iv) Plans that provide only for indemnity for
9 hospital confinement;
10 (v) Long-term-care-only plans that do not include
11 pharmacy benefits;
12 (vi) Other limited-benefit health insurance policies
13 or plans;
14 (vii) Health benefit plans provided under Arkansas
15 Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et
16 seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;
17 (viii) A plan that provides only dental benefits or
18 eye and vision care benefits; or
19 (ix) A program or plan authorized and funded under
20 42 U.S.C. § 1396a et seq.;

21 (4)(A) "Healthcare insurer" means an insurance company that is
22 subject to state law regulating insurance and offers health insurance
23 coverage under 42 U.S.C. § 300gg-91, as it existed on January 1, 2021, a
24 health maintenance organization, or a hospital and medical service
25 corporation.

26 (B) "Healthcare insurer" does not include an entity that
27 provides only dental benefits or eye and vision care benefits;

28 (5) "Healthcare service" means an item or service provided to an
29 individual for the purpose of preventing, alleviating, curing, or healing
30 illness, injury, or physical disability; and

31 (6) "Person" means a natural person, corporation, mutual
32 company, unincorporated association, partnership, joint venture, limited
33 liability company, trust, estate, foundation, not-for-profit corporation,
34 unincorporated organization, government, or governmental subdivision or
35 agency.

36

1 23-79-2103. Fairness in cost sharing.

2 (a)(1) When calculating an enrollee's contribution to any applicable
3 cost-sharing requirement, a healthcare insurer shall include any cost-sharing
4 amounts paid by the enrollee or on behalf of the enrollee by another person.

5 (2) The cost-sharing requirement under subdivision (a)(1) of
6 this section does not apply for cost-sharing of a prescription drug if a
7 name-brand prescription drug is prescribed and the prescribed drug:

8 (A) Is not considered to be medically necessary by the
9 prescriber; and

10 (B) Has a medically appropriate generic prescription drug
11 equivalent.

12 (b)(1) Except as provided in subdivision (b)(2) of this section, this
13 section applies to a health benefit plan that is entered into, amended,
14 extended, or renewed on or after January 1, 2022.

15 (2)(A) Benefits offered through a health benefit plan under the
16 Evidenced-Based Prescription Drug Program of the College of Pharmacy of the
17 University of Arkansas Medical Sciences shall satisfy the requirements of
18 this act beginning on and after January 1, 2024, if the Insurance
19 Commissioner reports a failure to comply with this section to the Legislative
20 Council.

21 (B)(i) Beginning on January 1, 2022, the Director of the
22 Evidenced-Based Prescription Drug Program of the College of Pharmacy of the
23 University of Arkansas Medical Sciences shall report quarterly to the
24 commissioner, Arkansas Legislative Audit, and the Legislative Council
25 concerning details of plan savings and how the process that is used benefits
26 an enrollee and the offered plan.

27 (ii) The report described in subdivision
28 (b)(2)(B)(i) of this section shall include the amount of enrollee savings,
29 plan-specific data on the amount of manufacturer rebates received, and how
30 the manufacturer rebates were applied in each plan for which the program is
31 contracted to administer a prescription drug benefit.

32 (c) The General Assembly intends for this section to regulate a
33 healthcare insurer only to the extent permissible under applicable law.

34
35 23-79-2104. Rules

36 (a) The Insurance Commissioner shall promulgate rules necessary to

1 carry out this subchapter.

2 (b) The rules promulgated under this section shall require a
3 healthcare insurer and the Director of the Evidenced-Based Prescription Drug
4 Program of the College of Pharmacy of the University of Arkansas Medical
5 Sciences to submit to the commissioner plan-specific information related to
6 savings and accountability to document how enrollees are realizing a cost
7 savings under each plan.

8
9 SECTION 3. Arkansas Code Title 23, Chapter 92, Subchapter 5, is
10 amended to add an additional section to read as follows:

11 23-92-511. Fairness in cost sharing – Definitions.

12 (a) As used in this section:

13 (1) "Cost-sharing requirement" means a copayment, coinsurance,
14 deductible, or annual limitation on cost sharing, including without
15 limitation a limitation subject to the Patient Protection and Affordable Care
16 Act, Pub. L. No. 111-148, that is required by or on behalf of an enrollee in
17 order to receive a specific healthcare service, including a prescription
18 drug, covered by a health benefit plan;

19 (2) "Enrollee" means an individual entitled to healthcare
20 services from a healthcare insurer;

21 (3)(A) "Health benefit plan" means any individual, blanket, or
22 group plan, policy, or contract for healthcare services issued or delivered
23 by a healthcare insurer in this state.

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

- 25 (i) Accident-only plans;
26 (ii) Specified disease plans;
27 (iii) Disability income plans;
28 (iv) Plans that provide only for indemnity for
29 hospital confinement;
30 (v) Long-term-care-only plans that do not include
31 pharmacy benefits;
32 (vi) Other limited-benefit health insurance policies
33 or plans;
34 (vii) Health benefit plans provided under Arkansas
35 Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et
36 seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

1 (viii) A plan that provides only dental benefits or
2 eye and vision care benefits; or

3 (ix) A program or plan authorized and funded under
4 42 U.S.C. § 1396a et seq.;

5 (4)(A) "Healthcare insurer" means an insurance company that is
6 subject to state law regulating insurance and offers health insurance
7 coverage under 42 U.S.C. § 300gg-91, as it existed on January 1, 2021, a
8 health maintenance organization, or a hospital and medical service
9 corporation.

10 (B) "Healthcare insurer" does not include an entity that
11 provides only dental benefits or eye and vision care benefits;

12 (5) "Healthcare service" means an item or service provided to an
13 individual for the purpose of preventing, alleviating, curing, or healing
14 human illness, injury, or physical disability; and

15 (6) "Person" means a natural person, corporation, mutual
16 company, unincorporated association, partnership, joint venture, limited
17 liability company, trust, estate, foundation, not-for-profit corporation,
18 unincorporated organization, government, or governmental subdivision or
19 agency.

20 (b)(1) When calculating an enrollee's contribution to any applicable
21 cost-sharing requirement, a healthcare insurer shall include any cost-sharing
22 amounts paid by the enrollee or on behalf of the enrollee by another person.

23 (2) The cost-sharing requirement under subdivision (b)(1) of
24 this section does not apply for cost-sharing of a prescription drug if a
25 name-brand prescription drug is prescribed and the prescribed drug:

26 (A) Is not considered to be medically necessary by the
27 prescriber; and

28 (B) Has a medically appropriate generic prescription drug
29 equivalent. (c)(1) Except as provided in subdivision (c)(2) of this section,
30 this section applies to a health benefit plan that is entered into, amended,
31 extended, or renewed on or after January 1, 2022.

32 (2)(A) Benefits offered through a health benefit plan under the
33 Evidenced-Based Prescription Drug Program of the College of Pharmacy of the
34 University of Arkansas Medical Sciences shall satisfy the requirements of
35 this act beginning on and after January 1, 2024, if the Insurance
36 Commissioner reports a failure to comply with this section to the Legislative

1 Council.

2 (B)(i) Beginning on January 1, 2022, the Director of the
3 Evidenced-Based Prescription Drug Program of the College of Pharmacy of the
4 University of Arkansas Medical Sciences shall report quarterly to the
5 commissioner, Arkansas Legislative Audit, and the Legislative Council
6 concerning details of plan savings and how the process that is used benefits
7 an enrollee and the offered plan.

8 (ii) The report described in subdivision
9 (c)(2)(B)(i) of this section shall include the amount of enrollee savings,
10 plan-specific data on the amount of manufacturer rebates received, and how
11 the manufacturer rebates were applied in each plan for which the program is
12 contracted to administer a prescription drug benefit.

13 (d)(1) The commissioner shall promulgate rules necessary to carry out
14 this section.

15 (2) The rules promulgated under this section shall require a
16 healthcare insurer and the director to submit plan-specific information
17 related to savings and accountability to document how enrollees are realizing
18 a cost savings under each plan.

19 (e) The General Assembly intends for this section to regulate a
20 healthcare insurer only to the extent permissible under applicable law.

21
22 SECTION 4. TEMPORARY LANGUAGE. DO NOT CODIFY. Rules.

23 (a) The Insurance Commissioner shall promulgate rules necessary to
24 implement this act.

25 (b)(1) When adopting the initial rules to implement this act, the
26 final rule shall be filed with the Secretary of State for adoption under §
27 25-15-204(f):

28 (A) On or before January 1, 2022; or

29 (B) If approval under § 10-3-309 has not occurred by
30 January 1, 2022, as soon as practicable after approval under § 10-3-309.

31 (2) The commissioner shall file the proposed rule with the
32 Legislative Council under § 10-3-309(c) sufficiently in advance of January 1,
33 2022, so that the Legislative Council may consider the rule for approval
34 before January 1, 2022.

35
36 APPROVED: 4/27/21