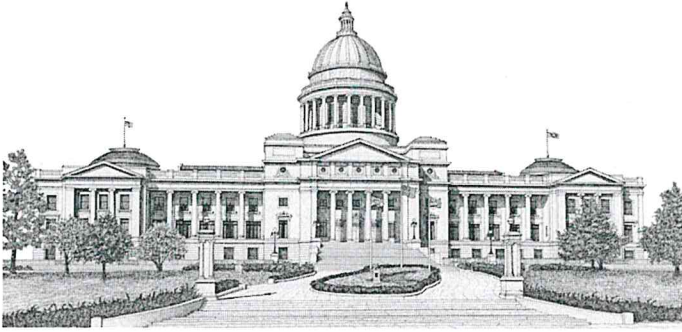


# ARKANSAS REGISTER

## Transmittal Sheet

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



Secretary of State

**John Thurston**

500 Woodlane, Suite 026

Little Rock, Arkansas 72201-1094

(501) 682-5070

[www.sos.arkansas.gov](http://www.sos.arkansas.gov)



For Office

Use Only:

Effective Date \_\_\_\_\_ Code Number \_\_\_\_\_

Name of Agency Arkansas Insurance Department

Department Arkansas Department of Commerce

Contact Booth Rand, Chief Legal Counsel E-mail booth.rand@arkansas.gov Phone 501-371-2827

Statutory Authority for Promulgating Rules Ark. Code Ann. §23-92-606

Rule Title: Final Rule 123: "340B Drug Program Nondiscrimination Requirements"

Intended Effective Date  
(Check One)

☐ Emergency (ACA 25-15-204)

☒ 10 Days After Filing (ACA 25-15-204)

☐ Other \_\_\_\_\_  
(Must be more than 10 days after filing date.)

Legal Notice Published .....

Final Date for Public Comment .....

Reviewed by Legislative Council .....

Adopted by State Agency .....

Date

July 31, Aug 1 & Aug 2, 2022

August 15, 2022

September 15, 2022

September 19, 2022

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

**Clara D. Mezza**

[clara.mezza@arkansas.gov](mailto:clara.mezza@arkansas.gov)

**9-19-2022**

Contact Person

E-mail Address

Date

### CERTIFICATION OF AUTHORIZED OFFICER

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

*Clara Mezza*

Signature

501-683-3497

[clara.mezza@arkansas.gov](mailto:clara.mezza@arkansas.gov)

Phone Number

E-mail Address

Insurance Administrative Coordinator

Title

09/19/2022

Date

## **RULE 123**

### **340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS**

- I. AUTHORITY**
- II. DEFINITIONS**
- III. THIRD PARTY REQUIREMENTS**
- IV. THIRD PARTY AND PHARMACEUTICAL MANUFACTURER-PROHIBITIONS**
- V. PHARMACY CLAIMS**
- VI. PENALTIES**
- VII. EFFECTIVE DATE**

#### **I. AUTHORITY**

This rule is issued pursuant to Ark. Code Ann. § 23-92-606 which mandates that the Insurance Commissioner ("Commissioner") shall promulgate a rule to implement the subchapter pertaining to the 340B Drug Pricing Nondiscrimination Act.

#### **II. DEFINITIONS**

As used in this Rule:

- (1) "Arkansas-based community pharmacy" means a Pharmacy licensed and located in this State;
- (2) "Covered entity" means an entity that meets the 340B Drug Pricing Program's eligibility requirements found at 42 U.S.C. § 256b(a)(4) and is enrolled in the 340B Drug Pricing Program;
- (3) "Patient" means an individual who has an established relationship with a covered entity and is seeking medical diagnosis and treatment from the covered entity;
- (4) "Pharmacy" means the same as defined in § 17-92-101;
- (5) "Provider" means a licensed pharmacist as defined in § 17-92-101;
- (6)(A) "Third party" means:
  - (i) A payor or the payor's intermediary;
  - or (ii) A pharmacy benefits manager.

(B) "Third party" does not include:

(i) The Arkansas Medicaid Program;

(ii) A risk-based provider organization as established under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.; or

(iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan; and

(7) "340B drug pricing" means the acquisition and delivery of 340B-priced drugs as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

### **III. THIRD PARTY REQUIREMENTS**

A third party shall:

(1) Inform a patient that the patient is not required to use a mail-order pharmacy;

(2) Obtain a signed waiver from a patient before allowing the use of a mail-order pharmacy;

(3) Make drug formulary and coverage decisions based on the third party's normal course of business;

(4) Allow a patient the freedom to use any pharmacy or any provider the patient chooses, whether or not the pharmacy participates in 340B drug pricing; and

(5) Eliminate discriminatory contracting as it relates to:

(A) Transferring the benefit of 340B drug-pricing savings from one (1) entity, including critical access hospitals, federally qualified health centers, other hospitals, or 340B drug-pricing participants and their underserved patients, to another entity, including without limitation pharmacy benefits managers, private insurers, and managed care organizations;

(B) Pricing that occurs when offering a lower reimbursement for a drug purchased under 340B drug pricing than for the same drug not purchased under 340B drug pricing;

(C) Refusal to cover drugs purchased under 340B drug pricing;

(D) Refusal to allow 340B drug-pricing pharmacies to participate in networks; and

(E) Charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing.

### **IV. THIRD PARTY AND PHARMACEUTICAL MANUFACTURER-PROHIBITIONS**

(a) A third party shall not:

- (1) Coerce a patient into using a mail-order pharmacy;
  - (2) Require a patient to use a mail-order pharmacy;
  - (3) Discriminate, lower the reimbursement, or impose any separate terms upon a pharmacy in any other third party contract on the basis that a pharmacy participates in 340B drug pricing;
  - (4) Require a pharmacy to reverse, resubmit, or clarify a 340B drug-pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing;
  - (5) Require a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim unless the drug or claim is being billed to the fee-for-service Arkansas Medicaid Program;
  - (6) Modify a patient's copayment on the basis of a pharmacy's participation in 340B drug pricing;
  - (7) Exclude a pharmacy from a network on the basis of the pharmacy's participation in 340B drug pricing;
  - (8) Establish or set network adequacy requirements based on 340B drug pricing participation by a provider or a pharmacy; or
  - (9) Prohibit an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing from participating in the third party's provider network on the basis of participation in 340B drug pricing.
- (b) A third party that is a pharmacy benefits manager shall not base the drug formulary or drug coverage decisions upon the 340B drug-pricing status of a drug, including price or availability, or whether a dispensing pharmacy participates in 340B drug pricing.
- (c) A pharmaceutical manufacturer shall not:
- (1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or
  - (2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

## **V. PHARMACY CLAIMS**

All pharmacy claims processed by a pharmacy that participates in 340B drug pricing are final at the point of adjudication.

## **VI. PENALTIES**

The penalties, actions or orders, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

## **VII. EFFECTIVE DATE**

This Rule is effective after review and approval by the Arkansas Legislative Council, ten (10) days after filing of the approved Rule with the Arkansas Secretary of State.

  
\_\_\_\_\_  
**ALAN MCCLAIN**  
**INSURANCE COMMISSIONER**

  
\_\_\_\_\_  
**DATE**